

CMS RELEASES NEW POLICY MEMOS ADDRESSING “OFF LABEL” DRUG USE & RATED AGES REGARDING MEDICARE SET-ASIDE PROPOSALS

*Assessing CMS’ May 14, 2010 & June 8, 2010 Policy Memos
& Their Potential Impact on the MSA Process*

By:
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The Centers for Medicare & Medicaid Services (CMS) has released two new policy memos dated May 14, 2010 (hereinafter *May Memo*) and June 8, 2010 (hereinafter *June Memo*) addressing the separate issues of (a) off label and/or unlabeled outpatient drug uses and (b) rated ages in relation to the agency’s Workers’ Compensation Medicare Set-Aside (MSA) program. These newly released memos are the agency’s 13th and 14th policy memos regarding its workers’ compensation MSA process.

A copy of the *May Memo* may be obtained at http://www.nuquestbridgepointe.com/docs/uploads/may_14_2010_cms_memo.pdf.

A copy of the *June Memo* may be obtained at http://www.nuquestbridgepointe.com/news/uploads/june_8_memo-1.pdf.

The *May Memo* revises specific aspects of CMS’ prescription drug policy regarding MSAs as set forth in its April 3, 2009 policy memorandum, and in a document entitled “CMS Prescription Drug Set-Aside Guidance for Submitters Effective: June 1, 2009” (RX Guidance Document).¹

Through the *May Memo*, CMS intends to “clarify” when off label and/or unlabeled drugs are considered covered

by Medicare Part D and, thus, appropriately includable as part of a MSA proposal. CMS’ new off label drug use policy commences June 1, 2010 as that date is more specifically referenced in the *May Memo*.

In the *May Memo* CMS also replaced its previously required rated age “certification statement” with a more stringent statement. However, this change was short lived as CMS thereafter released its *June Memo* further “revising” the rated age “certification statement” required to be included as part of MSA proposals.

This article dissects and analyzes the newly released memos in an effort to understand CMS’ new policies and their potential impact on the MSA process. As part of this analysis, it is absolutely crucial to keep in mind that these new policies are in their infancy, and it remains unknown at this time how CMS will actually *interpret* and *apply* the new policies. This is particularly pertinent regarding CMS’ changes related to off label drug usage.

On this latter point, it is important not to forget the hard lesson learned last year in relation to CMS’ release of its RX policies (or, for that matter, any number of other instances over the past decade) that there can be a world of difference between what may seem to be indicated in *writing* from how CMS will ultimately *interpret* and *apply* the policies in practice. Thus, jumping to general

conclusions should be avoided until the industry has the benefit of learning first hand how CMS intends to apply its new policies.

With this understanding, the author outlines the analysis as follows:

Part I: CMS' New "Off Label" Drug Use Policy & MSAs – *A Step in the Right Direction*

Part II: CMS' Rated Age "Certification Statement" – *Understanding What Is Required*

PART I

CMS' New "Off Label" Drug Use Policy & MSAs – *A Step in the Right Direction*

Brief Background & CMS' New Approach

In order to more fully assess the changes made by the *May Memo*, it is first necessary to understand how CMS has been approaching off label drug usage up until this point.

CMS initially addressed off label drug usage in the 2009 RX Guidance document (Point #5) which states as follows:

#5. Off-label use: Off-label use of medications in the United States is both legal and common. Once a drug has been approved for sale by the Food and Drug Administration ("FDA") for one purpose, physicians are free to prescribe it for any other purpose that in their professional judgment is both safe and effective. Physicians are not limited to prescribing a drug only for official, FDA-approved indications.

In practice, CMS has basically been requiring the inclusion of *any* off label drug usage as part of the MSA calculation, regardless of whether or not said usage is approved under the FDA, or otherwise covered under Part D. For obvious reasons, legitimate questions surfaced regarding the propriety of this practice. From a practical standpoint, CMS' approach has drastically raised the amount of the RX calculation in many instances.

Per the *May Memo*, the inclusion of off label drug usage as part of a MSA proposal will now be determined by a more circumscribed and limited standard. As part of the agency's attempt to "clarify" this issue, it has provided

the following definition and guidance in terms of what are to be considered covered Part D drugs:

Definition of Covered Part D Drugs:

A "covered Part D drug" is "a drug that may be dispensed only upon a prescription and that is described in [certain referenced sections under the United States Code; citations omitted]."

For a Part D drug to be covered by Medicare, and thus included properly in a WCMSA, the drug should be prescribed for an outpatient use that is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(I) of 42 U.S.C. Section 1396r-8. (Emphasis by CMS).

This statement can be interpreted to indicate that effective June 1, 2010 (as that date is more specifically defined by CMS) whether or not "off-label" usage will need to be allocated will depend on whether such use is (a) prescribed for an outpatient use that is approved under the FDA, or (b) supported by one or more citations included or approved for inclusion in any of the compendia.²

This interpretation has been confirmed to NuQuest by CMS. In relation thereto, CMS advised NuQuest that if a particular drug is FDA approved, but not for the prescribed use, then the compendia should be consulted for any applicable supporting citations. If one of the compendia cites the drug for the prescribed off label usage then it is considered Medicare allowable and includable as part of the MSA calculation. If, by contrast, the usage is *not* supported by the compendia then the drug will be considered as *not* allowable and properly excludable from the MSA proposal.

On the surface, CMS' new policy can be viewed as a step in the right direction in terms of potentially reducing the RX calculation. For example, this could have a significant impact in reducing costs in regard to certain expensive drugs, such as Actiq or Fentora.

While this new policy is an improvement, it is important to note that the new policy does *not* necessarily ban all off-label usage from possible inclusion in a MSA proposal. Furthermore, there is the possibility that interpretational differences could arise between the MSA preparer and CMS in terms of whether or not the compendia support a particular off-label usage.

Implementation of CMS' New Off-Label Drug Use Policy

CMS' new policies regarding off-label drug use are effective June 1, 2010 as more specifically outlined in this section.

The *May Memo* addresses how CMS will handle the situation where a settlement *prior* to June 1, 2010 contained non-covered Part D drugs as part of a MSA. Furthermore, CMS addresses how it will address cases *not* settled prior to June 1, 2010 but which include non-covered Part D drugs as part of the MSA.

In the *May Memo*, CMS states as follows regarding implementation of its new off label drug use policy (the author has numbered the listed situations for easier identification):

1. **Effective June 1, 2010**, for those workers' compensation (WC) settlements effectuated prior to June 1, 2010, and where the settlement included non-covered Part D drugs as part of the WCMSA, CMS will consider funds spent for those non-covered Part D drugs by beneficiaries and claimants as being an appropriate expenditure of funds as part of the WCMSA.
2. For those WC claims that were **not settled prior to June 1, 2010**, and where the settlement includes non-covered Part D drugs as part of the WCMSA, CMS will consider a re-pricing of those cases that included non-covered Part D drugs. Once CMS performs a re-pricing of the WCMSA, beneficiaries and claimants may not use funds from their WCMSA to pay for non-covered Part D drugs. Doing so constitutes an inappropriate expenditure of WCMSA funds.
3. For those WC settlements **resolved on or after June 1, 2010**, and where the settlement does not include non-covered Part D drugs as part of the WCMSA, beneficiaries and claimants may not use funds from their WCMSA to pay for those non-covered Part D drugs. Again, doing so constitutes an inappropriate expenditure of funds as part of the WCMSA.

As will be noted, situation #1 contemplates the instance where the MSA included non covered Part D drugs regarding a settlement prior to June 1, 2010. In this situation CMS indicates that it will consider funds spent for those non-covered Part D as being proper expenditures from the MSA. By contrast, if the MSA did *not* include non-covered Part D drugs and the case settled prior to

June 1, 2010, CMS has advised NuQuest that in that particular instance if a claimant is prescribed a non-covered Part D drug for their related injury, he/she *cannot* use funds from their MSA to pay for those drugs. This important distinction should be duly noted.

With regard to situation #2, for those cases that were *not* settled prior to June 1, 2010 which contained non-covered Part D drugs, CMS is allowing the industry to resubmit any MSA previously reviewed by the agency for re-pricing. Accordingly, it would make sense to determine which cases may be eligible for re-pricing as this could potentially reduce the MSA allocation amount.

PART II

CMS' Rated Age "Certification Statement" – *Understanding What Is Required*

CMS has significantly revised its rated age policy and the corresponding rated age "certification statement" that must be included as part of a MSA proposal. To better appreciate and understand the new policy directives, it is helpful to view these changes in wider context.

This saga begins with CMS' August 25, 2008 memo, requires analysis of the short lived policy statements contained in the *May Memo*, and ends with CMS' recently released (and current) policy proclamations as contained in the *June Memo*:

August 25, 2008 Policy Memo

CMS' rated age policy as outlined in the August 25, 2008 memo stated as follows:

To protect the Medicare Trust Fund, a set-aside arrangement should be funded based on the life expectancy of the individual unless the State law specifically limits the length of time that WC covers work-related conditions.

Unless a submitter furnishes acceptable proof of a Rated Age for a claimant, CMS will estimate the claimant's remaining life expectancy using Actual Age. Acceptable proof of Rated Ages includes independent rated ages on the letterhead of an insurance carrier or settlement broker and a statement from the submitter that all rated ages obtained on the claimant have been included.

This policy remained in effect until CMS' release of the *May Memo* this year.

May 14, 2010 Policy Memo

Through the *May Memo*, CMS then rescinded the August 25, 2008 memo replacing it with a more stringent rated age "certification statement."

CMS' rated age policy as contained in the *May Memo* states as follows:

The previous Rated Age (RA) statement from the submitter that all rated ages obtained on the claimant have been included is now rescinded.

Hereafter, to mitigate confusion and eliminate ambiguous statements concerning RA, all WCMSA submitters must include the following certification statement in association with RA information:

"Our organization certifies that all rated ages obtained on the claimant, at any time during that individual claimant's lifetime, have been included as part of this submission to the Centers for Medicare & Medicaid Services."

The CMS will not accept any variation or substitute wording. If a submitter is including RA information in its WCMSA proposal, the new certification language must be included as written, with no exceptions. If this appropriate statement is not included as part of the WCMSA proposal, CMS will not accept the RA provided. Instead, CMS will estimate the claimant's remaining life expectancy using Actual Age. (Emphasis Added)

This policy change immediately raised several legitimate questions and issues in that a literal interpretation of the statement would essentially require a submitter to attest to absolute facts over a claimant's "lifetime" that would be difficult or impossible to ascertain in many instances.

In this regard, placing a requirement on a submitter to certify that *all* rated ages ever possibly obtained over the claimant's "lifetime" was widely viewed as unreasonable and impractical. In essence, the submitter would be placed in the peculiar position of having to affirm or discover facts and information that were wholly *unrelated* to the subject claim that could span several years or decades, which would very likely not even be obtainable due to discovery limitations, privacy preclusions, or informational purging, and which would likely be outside of the submitter's control. Furthermore, the submit-

ter would be forced to rely upon information and recollections of third parties which may be faulty, despite even the best intentions. For example, the claimant him/herself may have not even been aware that somewhere over the scope of his/her life someone had requested a rated age.

Aside from issues of access and reasonableness, sound questions were raised as to what legitimate purpose would be served of having to discover and then inform CMS of rated ages that were obtained *years prior* to the subject claim, and for reasons totally unrelated to a specific claim that was being evaluated for MSA purposes in 2010. For example, what bearing or relevance would a rated age from 1994 have with respect to a claim being evaluated for MSA purposes in 2010? These questions became even more baffling in light of the fact that CMS, ironically, has basically been using a median rated age based on what the agency considers "valid" rated ages which typically fall within a very *limited* time period.

As such, the policy announced in the *May Memo* was roundly criticized on a number of levels, particularly with respect to issues concerning practicality, reasonableness and enforceability.³

June 8, 2010 Policy Memo (CMS' Current Rated Age Policy)

It is widely believed that the type of questions and issues raised by the *May Memo* discussed above served as the catalyst for CMS to re-examine its rated age policy as stated in the *May Memo* and to thereby revise same via the *June Memo*.

Thus, through the *June Memo*, CMS' current rated age policy and the related certification statement that must be included as part of a MSA proposal is as follows:

Effective immediately the Rated Age (RA) certification required by the May 14th memorandum is revised to:

"Our organization certifies that all rated ages we have obtained and/or have knowledge of regarding this claimant, and generated at any time on or after the Date of Incident for the alleged accident/illness/injury/incident at issue, have been included as part of this submission of a proposed amount for a Workers' Compensation Medicare Set-Aside Arrangement (WCMSA) to the Centers for Medicare & Medicaid Services." (Emphasis Added).

As will be noted, the new statement is more reasonably limited in terms of scope (*all rated ages we have obtained and/or have knowledge of regarding this claimant, and generated at any time on or after the date of incident*), and in terms of relation (*for the alleged accident/illness/injury/incident at issue*) than the “lifetime” attestation requirement contained in the *May Memo*.

It should be noted that CMS will *not* permit any modification to the certification statement. Furthermore, all other requirements regarding acceptable proof of a rated age remain. On these points, the *June Memo* states:

The CMS will not accept any variation or substitute wording. If a submitter is including RA information in its WCMSA proposal, the revised certification language must be included as written, with no exceptions. If this specific language is not included as part of the WCMSA proposal, CMS will not accept the RA provided. Instead, CMS will estimate the claimant’s remaining life expectancy using Actual Age. For the convenience of those already in the process of submitting a proposal, CMS will continue to accept the certification language required by the May 14, 2010 memorandum for proposals received up through and inclusive of June 30, 2010.

Note:

All other requirements of acceptable proof of a Rated Age for a claimant are unchanged. Acceptable proof of Rated Age is demonstrated through inclusion of independent rated ages on the letterhead of an insurance carrier or settlement broker.

Overall, the revised certification statement contained in the *June Memo* is a more reasonable, workable and realistic standard, and should help alleviate the concerns raised by the *May Memo* in regard to the continued feasibility of using rated ages as a possible tool to help reduce MSA allocation amounts.

Conclusion

CMS’ new off label drug use policy is certainly a welcomed step which could play a pivotal role in potentially reducing the RX calculation in certain situations. However, it is important to remember that this new poli-

cy relates to only *one* limited aspect of the overall RX calculation process, which may or may not even be applicable in a given case.

Unfortunately, a host of other issues and challenges still need to be overcome toward obtaining a greater degree of consistency and reasonableness in relation to CMS’ overall approach to the RX calculation process. Also, as cautioned above, how CMS will actually interpret and apply the new policy is a very important factor that remains unknown at this time. Thus, until this other shoe drops judging the true impact and effectiveness of this new policy really cannot be stated with any degree of accuracy.

On this note, caution and prudence should be exercised with respect to claims of “silver bullets” or other “cure all” solutions to this particular issue, or the RX problem in general. These claims have an understandable allure to an industry struggling to find answers. However, due diligence, serious probing and level-headed assessment should be employed before blindly jumping aboard any magic carpets.

The truth of the matter is that the complexity of the issue, coupled with CMS’ inconsistent and erratic practices, have created a process and problem whose magnitude simply defies and dwarfs any alleged “magic wand” answers. Any claims or approaches to the contrary should be closely scrutinized, as they would seem to cut against the grain of an informed, knowledgeable and reasoned assessment of current realities.

NuQuest will continue to develop logical, reasoned and realistic approaches to assist the industry in meeting the continuing and changing challenges posed by CMS’ RX policies.

NuQuest is working closely with a team of respected and knowledgeable pharmacists from Progressive Medical, Inc. to analyze the compendia to determine whether or not a particular off label use would be properly includable as part of a MSA proposal as part of its commitment to provide its customers with only exemplary professional services.

About the Author

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Endnotes

- ¹ For a detailed survey of these documents and CMS' RX policy in general, the reader may wish to consult the author's article *Prescription Drugs & The MSA – Understanding CMS' New RX Drug Policies, Practical Approaches for Claims Handling & Settlement*, NuQuest/Bridge Pointe "Settlement News," December, 2009.

This article can be obtained at
http://www.nuquestbridgepointe.com/news/uploads/december_2009_settlement_news.pdf

CMS' April 3, 2009 Memorandum may be obtained at
http://www.nuquestbridgepointe.com/docs/uploads/cms_memo_4-6-2009.pdf

CMS' RX Guidance Document may be obtained at
<http://www.nuquestbridgepointe.com/news/uploads/msarxguidance.pdf>

- ² The WCRC advised that they essentially use two compendia, *Drugdex Drug Point Micromedex*, Thomson Reuters and *AHFS Drug Information*. 2010. A third series, U.S. Pharmacopoeia Drug Information has reportedly been discontinued and the WCRC is no longer using same. The WCRC also advised that at this time it has no plans to provide the industry access to the compendia.
- ³ The author addressed these issues and questions in Part II of his article entitled *CMS Announces Important Policy Changes Regarding Off Label Drug Use & Rated Ages*, Settlement News, June, 2010. CMS' subsequent release of its *June Memo* essentially renders moot the discussion contained in Part II of the aforementioned article. CMS' *current* rated age policy is as outlined above in Part II of this June 29, 2010 edition of Settlement News.