

CMS ANNOUNCES IMPORTANT POLICY CHANGES REGARDING “OFF LABEL” DRUG USE & RATED AGES

*Analyzing CMS’ May 14, 2010 Policy Memorandum &
Assessing Its Potential Impact on the MSA Process*

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On May 19, 2010, the Centers for Medicare & Medicaid Services (CMS) released a new policy memorandum dated May 14, 2010 (hereinafter *May 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. The *May Memo* is the agency’s 13th memo 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.

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*. On another front, the *May Memo* rescinds CMS’ previous rated age policy and replaces it with what can be viewed as a more stringent standard.

While the *May Memo* was only recently released, it has already garnered significant interest and discussion. In

this frenzy, some have attempted to ascribe to their exclusive efforts whatever “victory” CMS’ new off label drug policy may represent. Fortunately, more reasoned voices have emerged rightfully clarifying that whatever influence on CMS the industry may have had is in actuality the result of larger and continuing efforts by many MSA companies, professionals, practitioners and industry groups (including NuQuest) which have all been working diligently toward achieving a more workable and equitable process.

In the spirit of a more reasoned discourse on the topic, this article dissects and analyzes the *May Memo* 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* (p. 2 - 3)
- Part II: CMS' New Rated Age Policy – *Assessing CMS' Requirements & Objectives* (p. 3 - 5)

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' New Rated Age Policy

Assessing CMS' Requirements & Objectives

CMS has announced a significant change to its rated age policy and has rescinded its previous rated age guidelines as contained in the August 25, 2008 memorandum.

CMS' *prior* rated age policy outlined in the August 25, 2008 memorandum 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.

Through the *May Memo*, CMS has now made what may be viewed as a significant change to the "certification statement" required to be included as part of a MSA submission.

CMS' new rated age policy as stated in the *May Memo* provides 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.

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

As will be noted, CMS’ new policy requires the submitter³ to certify that *all* rated ages obtained on the claimant *at any time during the claimant’s lifetime* have been included in conjunction with a MSA proposal.

A literal interpretation of CMS’ new “certification statement” suggests that the submitter is required to attest that all rated ages ever obtained on the claimant, no matter when procured and regardless of whether or not same were obtained in relation to the subject claim to which the MSA proposal pertains, are included as part of a MSA submission. The absence of qualifying language that would restrict the scope of the submitter’ obligation (i.e. language limiting attestation to only those rated ages obtained by the submitter; or language allowing the attestation to be premised upon the submitter’s or parties’ “best knowledge and belief;” or language otherwise accounting for the possibility that it may not be possible to make the determination) renders this statement quite disturbing on a number of levels.

Requiring a submitter to certify that *all* rated ages ever possibly obtained over the claimant’s “lifetime” is unreasonable and impractical for many reasons. In essence, the submitter is placed in the peculiar position where it

must affirm or discover facts and information that is wholly *unrelated* to the subject claim that could span several years or decades, which may not even be accessible due to discovery limitations, privacy preclusions, or informational purging, and which may very well be outside of its control. Furthermore, the submitter 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, legitimate questions are raised as to why CMS would be interested, for instance, in being informed about a rated age obtained in 1994 for a reason and in a context totally unrelated to a specific claim being evaluated for MSA purposes in 2010? (This, of course, again assumes the claimant even knew that this was done or remembered it was done; that there was a way to determine that a rated age was procured 16 years ago; and that there was even access to these records). What relevance or bearing would this realistically have for MSA calculation purposes in 2010? These questions become even more baffling in light of the fact that CMS, ironically, has up until this point been basically using a median rated age based on what the agency considers “valid” rated ages which typically fall within a very *limited* time period.

On a practical level, requiring “life time” attestation may very likely have the affect of reducing or eliminating rated age usage, as it may simply be impossible for the submitter (or the parties in the underlying case) to make this representation in absolute terms in all instances. In turn, the inability to utilize rated ages will likely result in higher MSA allocation calculations in many instances as the MSA projection would be based on the claimant’s standard age.

Another question that is starting to surface concerns CMS’ actual ability to obtain or otherwise track rated ages to assess compliance with the certification statement. (This question is presented by the author solely for purposes of overall academic assessment of the issue, and by no means is intended to suggest that this consideration alone should serve as the basis to determine how to appropriately proceed). With said caveat, the author is unaware at this time whether or not CMS has this capability, or how it otherwise plans to determine whether a submitter is in proper compliance. If the agency in fact has some method to obtain or track historical rated ages,

making some accessible to the public would make sense. If it does *not* have this ability, significant questions would seemingly be raised regarding overall objective, practicality and enforceability, as well as, the potential for arbitrary and capricious agency action.⁴

In the end analysis, CMS' new rated age policy is perplexing in the best light; from a less generous vantage point the policy dances at the doorstep of absurdity in that it does not seem to be reasonably calculated to serve any legitimate objective in the overall MSA process. If the agency's intent is to cease rated age usage, a more direct statement indicating such would have arguably been the better route.

Nonetheless, at this time the industry is left to address how best to approach this issue, which would seemingly call into play various ethical and practical considerations. As part of this process, it is important to keep in mind that it remains unknown how CMS plans on actually applying its new rated age policy. How CMS applies its new policy in practice will play a major role in terms of learning when and to what extent rated ages will in fact be accepted going forward.

Conclusion

Overall, CMS' new policies announced in the *May Memo* are probably best viewed as a mixed bag. On the one hand, the changes regarding off label drug use have the potential to reduce the RX calculation in certain situations. However, on the other hand, CMS' new rated age policy may very possibly reduce rated age usage which could result in higher MSA projections based on standard age calculations.

CMS' new off label drug use policy is certainly a welcomed step. However, it is important to remember that this new policy 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 continues its efforts to clarify the various issues presented by CMS' *May Memo* in order to provide its customers with the most accurate information. NuQuest will also continue to develop logical, reasoned and realistic approaches to assist the industry in meeting the challenges presented by CMS' new policies, and the RX issue in particular.

As part of its commitment to provide its customers with only exemplary professional services, 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.

Furthermore, NuQuest is, and will continue to, carefully review prior MSAs it has completed to provide its customers with recommendations as to whether or not re-pricing is appropriate. NuQuest is also working with its customers to develop the most workable and appropriate approach regarding CMS' new rated age certification statement.

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 From a technical standpoint, CMS' memo does not define the term "submitter." To a certain extent, the MSA vendor or other MSA professional that prepares the MSA may be viewed logically as the "submitter" as that entity prepares and submits the MSA proposal in the physical sense. As a practical matter, this entity, as opposed to the primary and/or claimant in the underlying case, would likely have the *least* access and recourse to undertake the type of discovery that would seemingly be required by CMS' new "certification statement." However, this particular issue could end up being a red herring in the sense that regardless of who CMS may actually intend to be the "submitter" in this context, the "submitter" may be required to attest to facts that simply defy determination in the *absolute* sense in which CMS' statement could be interpreted to indicate.

⁴ Along these same lines, some have raised the question of whether, and to what extent, CMS has the authority to penalize or otherwise sanction what it may consider a non-compliant submitter. From the author's viewpoint, this complex question, which is outside the scope of this article, is part and parcel of the much larger and very complicated issue regarding the nature, extent and scope of CMS' authority in regard to the *overall* MSA process. This determination involves consideration and analysis of several complicated legal principles, including aspects of administrative law, due process and other Constitutional considerations.