Instructions for Prescription Drug Formulary Tiering

General guidance applicable to all NQTL analyses: Every comparative analysis for each classification of benefits should be self-contained. In other words, it should not be necessary for the regulator to read through attachments or other separate policy documents to determine if the comparative analysis is sufficient. For any relevant document such as utilization management manuals, clinical policy bulletins, guidelines, criteria, etc., it is the responsibility of the plan/issuer to examine those documents and determine if there is comparability and no more stringent application between MH/SUD and medical/surgical. This is the fundamental expectation of comparative analysis: the plan/issuer examines all relevant materials and data, compares, contrasts, probes, and analyzes them and then explains what was revealed and how or why everything examined did or did not reveal compliance. Attachments and other documents may be submitted so that the regulator can corroborate the plan/issuer's findings and conclusions, but the plan/issuer should avoid responding to any step with "see attachments X, Y, and Z for proof of compliance". There will be select instances when the instructions for a particular step allow for the submission of attachments in lieu of analysis text.

Step 1: The specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification.

Guidance: If the plan or issuer does not have any formulary tiers or tier placement and inclusion is decided by state agency (or law), it is not necessary to complete a comparative analysis for this NQTL.

This step requires that the plan/issuer identify all coverage terms, policies, and procedures related to formulary tiering. It is understood that formulary tiering only applies in the prescription drug classification of benefits. The plan/issuer should identify its formulary tiers and briefly explain the difference among the various tiers. Given the sheer bulk of medications on any plan/issuer's formulary, a separate attachment may be submitted that contains each medication on the formulary and in which tier each medication falls. It is recommended, but not required, that the plan/issuer organize this attachment by tier rather than alphabetically. In other words, list each medication in tier 1, then each medication in tier 2, and then each medication in tier 3, and so on. A document organized alphabetically makes it much more difficult to get a sense of the scope of each tier.

Also, please list medications that were considered for the formulary but were not ultimately included. This does not require that the plan/issuer list every existing medication that is not on its formulary. It is understood there are new medications or older and more obsolete medications that often aren't under consideration for a plan/issuer's formulary. Simply list medications that were considered but were then excluded.

Step 2: The factors used to determine that the NQTL will apply to MH/SUD benefits and medical or surgical benefits.

Guidance: The plan/issuer should provide an all-inclusive list of the factors it utilizes to decide to which tiers medications will be assigned (including factors that determine that a medication will be excluded from the formulary, if applicable).

The plan/issuer should avoid using phrases such as "factors include…" or "factors may include…". The standard for this step is reporting the factors that **will** determine tier placement and inclusion. Phrasing that uses "include" or "may include" introduces uncertainty as to whether the listed factors actually were used or that there may be unlisted factors used. It is recommended, but not required, that the plan/issuer

have a grid or chart indicating which factor or factors led to the tier placement for each medication (or the medication's exclusion from the formulary). Given the bulk of medications in play, this may also be submitted as a separate attachment if the plan/issuer chooses to utilize it.

Step 3: The evidentiary standards used for the factors identified in step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to MH/SUD benefits and medical or surgical benefits.

Guidance: The plan/issuer must define each factor set forth in Step 2 and identify the applicable evidentiary standard and source for each factor. For example, quantitative factors such as value or projected costs savings must be defined in an appropriate manner and documentation and/or an illustration of the calculation provided as supporting information. When defining a qualitative factor, it is not sufficient to indicate a factor or component of an evidentiary standard such as "opportunity to improve quality" without explaining specifically what that means or how it is determined. In addition, the plan/issuer should identify whether or not certain factors or components of a evidentiary standard are given more weight or value than others and explain the basis to assert they are not weighted. That is, if multiple factors are utilized to determine the tier placement, are any of them alone sufficient to determine placement? Or are all or a combination of the factors required?

If a factor clearly involves some sort of threshold, such as "drug is considered low value either in terms of efficacy, safety or cost", the threshold must be clearly defined and articulated. In this example, at what point does "value" fall into the realm of "low" in terms of each of efficacy, safety, or cost? It is possible that there is a hard quantitative means of establishing this, but it is also understood that the parameters for the threshold could somewhat more qualitative (although no concept of "value" can ever be completely severed from a quantitative understanding).

In terms of other evidence relied upon to design tier placement, there obviously will be substantial amounts of evidence that the plan/issuer relies upon to inform which tiers medications are assigned to or if they are included on the formulary at all. It is not necessary to detail and describe every piece of evidence and every source for the evidence. However, it is necessary for the plan/issuer to explain clearly and in detail how and why it was able to determine that the evidence relied upon that helped determine MH/SUD medication tier placement (or inclusion) was comparable to and applied nor more stringently than that used for medical/surgical medications. This should consist of more than merely stating that the process is "the same" or there is "no differentiation" between MH/SUD and medical/surgical when the P&T committee meets. Even when no differentiation or distinction is made between MH/SUD and medical/surgical it is certainly possible that more stringent application could have still occurred for some MH/SUD medications (this could occur through random variation alone).

Step 4: The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to medical or surgical benefits in the benefits classification.

Guidance: Given that formulary tier placement is somewhat different than other NQTLs, the requirements of this step are modified. There is not a traditional in-operation phase like there is in prior authorization, concurrent review, or even step therapy. Also, much of the written components are likely covered in steps 2 and 3. The focus of this step should be on the processes by which the P&T committee (or other responsible entity) made decisions about where medications were placed on the formulary, or if they were included at all. Step 3 focused on the evidentiary standards and sources that stood as the

foundation for making decisions, this step should focus on the decision-making itself. There is no expectation that this be an exhaustive examination of every decision made; that is impractical. However, the plan/issuer's analysis should clearly show how the decisions made about MH/SUD tier placement/inclusion were comparable to an applied no more stringently than those made regarding medical/surgical placement/inclusion. In other words, while it is understood that all of this happens inclusively and is not done separately for MH/SUD versus medical/surgical, what has led the plan/issuer to conclusively determine that that decisions that were made regarding MH/SUD passed the NQTL tests?

Finally, it is understood that manufacturer rebates can play a significant role in tier placement (although not always). If this is the case, a sufficient and truthful comparative analysis should delve into it.

Step 5: The specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results of the analyses described in this subparagraph that indicate that the plan or coverage is or is not in compliance with this section.

Guidance: The plan/issuer should provide a reasoned discussion of its findings and conclusions identified in Steps 1 through 4 within the prescription drug classification, including any citations to specific evidence considered and results of analyses which demonstrate that the issuer is or is not in compliance with MHPAEA. Note that it is not valid to present summary conclusions as to compliance if the required information in the preceding steps is insufficient.

The required information in Step 5 is inclusive of a summary and conclusion. The summary should be a concise statement or account of the principal information and results of the analyses offered to demonstrate compliance. It should not introduce new information or analyses not presented in the foregoing Steps. The conclusion provided should not merely be a summary of the principal supporting information or a re-statement of the issuer's analysis; it should be a synthesis of the basis from the above required information and analyses which definitively demonstrates compliance as written and in operation.

If the plan/issuer has decided that it is not in compliance, it should describe any plan it has for corrective action.