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Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

**Re: CMS–4140–IFC**

**Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008**

Dear Sir or Madame:

Cenpatico Behavioral Health, LLC (Cenpatico) is writing to offer comments in response to the interim final rules ("IFRs") under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008. Cenpatico is a managed behavioral health and wellness organization (MBHO) which contracts with Managed Care Plans (MCPs) in eight states. Cenpatico promotes integrated, evidence based behavioral health services and is committed to mental health parity.

The IFRs were issued in the Federal Register on February 2, 2010, and are applicable to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010. Medicaid managed care plans offering substance abuse and mental health services must comply with the MHPAEA; however, the IFRs state that these regulations do not apply to MCPs and that additional guidance will be provided by the Centers for Medicare and Medicaid Services (CMS).

We appreciate the guidance provided by the IFRs regarding financial requirements and quantitative treatment limitations. However, we have concerns that the IFRs exceed the scope of both MHPAEA's terms and Congressional intent and greatly undermine the very structures and procedures that have been successfully used in the management of public sector behavioral health services.

In response to the IFRs, Cenpatico recommends the Agencies make the following important changes:

**1. Withdraw the IFRs and republish them as proposed regulations.**

The IFRs require far-reaching changes in the way in which mental health and substance use disorder benefits are provided and managed. Most of these changes could not reasonably have been foreseen based on a reading of the statute. In similar situations, an industry being subjected to new and far-reaching rules would expect to be provided with the ability to review specific Agency proposals and to comment directly on the positions the Agency is proposing to take before those positions become final in any way. This notice and comment process, codified in the Administrative Procedure Act, provides the surest way to publication of final rules that equitably set standards for all persons affected by the regulations.

Despite this, the Agencies have short-circuited the process in the present situation. Although the Agencies issued a Request for Information (RFI), this was merely an inquiry process designed to educate the agencies about this complex area. It was in no way a substitute for a real notice-and-comment process. This defective process has produced an IFR which, as detailed below, is confusing, ineffective and may actually inhibit rather than advance true parity.

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Cenpatico believes that the only way to remedy this situation is for the Agencies to withdraw the IFRs and republish them in proposed form. Taking such a step would not work to the disadvantage of any group or individual affected by MHPAEA. The statute is self-executing, and the statutory mental health and substance abuse disorder standards do not require regulations to become effective. The Agencies themselves have recognized that compliance efforts by companies involved in the administration and management of the mental health and substance abuse disorder benefits are on-going. Although the Agencies state that they issued an IFR due to the need for guidance, the Agencies' rush to publication has produced a regulation that confuses rather than clarifies. Cenpatico urges the Agencies to take this reasonable step and reissue the regulation in proposed form so that all persons and entities affected by MHPAEA can be heard on an equitable basis.

**2. Alternatively, postpone the effective date of the IFRs until July 1, 2011.**

The IFRs are comprehensive and complex regulations that require many changes in the way Cenpatico provides services. Congress recognized that MHPAEA would require significant changes and therefore delayed its effective date, presuming that the Agencies would use the one year delay to propose and finalize regulations and thereby give the industry both input into the regulatory process and time to adjust to any changes necessitated by the regulations. Despite this long time frame, the agencies did not issue any guidance at all until the issuance of the IFRs and then provided little or no time for the industry to begin efforts to comply with the new standards. Indeed, the Agencies recognize at many places in the preamble to the IFRs that they did not have sufficient information to provide detailed guidance or examples, or in some cases, to provide any guidance at all.

Cenpatico believes that the Agencies should agree to a one year postponement of the applicability date of the IFRs, so that application of the standards in the IFR will begin for plan years beginning on or after July 1, 2011. This would have the dual benefit of providing adequate time for the industry as it develops its compliance mechanisms. The Agencies would also benefit from this extended timeline by allowing time for a thorough review of the comments received in response to the IFR. Ideally, such a postponement would also facilitate the issuance of a final regulation reflecting the comments from all interested parties before the IFR applicability date.

**3. Eliminate non-quantitative treatment limitations (NQTLs)**

The general parity rule set forth in section (c)(2)(i) of the IFRs states that a plan that covers both medical/surgical and mental health/substance abuse care may not apply any financial requirement or treatment limitation for mental health/substance abuse care that is more restrictive than the predominant financial requirement or treatment limitation applied to substantially all medical/surgical benefits in the same classification. However, the Agencies diverged from the statutory approach by including a definition of "treatment limitations" through the use of the term "Non-quantitative Treatment Limitations" ("NQTLs"). This term is not fully defined, but instead is the subject of an "illustrative list" of practices provided in section (c)(4)(ii) of the IFRs.

Cenpatico urges the Agencies to eliminate the NQTL category from the treatment limitations subject to the parity rule for the following reasons:

(a) The inclusion of the NQTL category exceeds the statutory authority and legislative intent behind MHPAEA. By its terms and legislative history, MHPAEA is a statute with limits on the extent of the practices and procedures that it covers. By including NQTLs and subjecting them to parity analysis, the IFRs negate the language in MHPAEA and apply parity in ways never intended by Congress;

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(b) NQTL practices cannot be meaningfully assessed under the "substantially all" and "predominant" tests mandated by Congress. Several of the practices listed in the NQTL illustrative list (e.g., provider reimbursement, network credentialing, formulary development) are structural matters that apply to all activities of the behavioral health rather than limitations on treatment. Other practices (e.g., step therapies, requirement to finish a course of treatment) are individual therapeutic tools available for all patients but only used on a case-by-case basis, so they are difficult to assess as a numerical matter;

(c) The inclusion of NQTL practices undermines the reasoning and financial analyses enumerated by the Agencies themselves in the preamble to the IFRs. The Agencies conclude that concurrent review of mental health/substance abuse benefits, although clinically justified in certain individual instances, cannot be applied generally because it is not comparable to retrospective review applied for medical/surgical benefits. In other words, the use of these tools — tools that have been instrumental in producing the favorable cost savings results on which the Agencies rely -- will be open to constant second-guessing, rendering their continued use problematic for Cenpatico. If implemented, the inclusion of NQTLs in the regulations will therefore markedly change the mental health and substance abuse care marketplace, rendering the Agencies' financial projections questionable at best and placing a significant cost burden associated the inclusion of NQTLs in the regulations on Cenpatico and other MBHOs;

(d) The Agencies ignore the vast differences between mental health/substance abuse care and medical/surgical care by essentially forcing MBHOs to adopt incongruent standards from the medical/surgical industry. The Agencies recognize that "not all treatments or treatment settings for mental health conditions or substance abuse disorders correspond to those for medical/surgical settings." 75 Fed. Reg. at 5416. However, by requiring that the mental health and substance abuse NQTLs must be "comparable to" limitations in the medical/surgical area, the Agencies arbitrarily combine the two areas, ignoring the fact that (at least with respect to NQTLs) requiring comparability is an attempt at equating apples with oranges. Essentially, this is a mandate that only those care management processes and procedures used for medical/surgical benefits can be employed in the mental health and substance abuse area. Whereas quantitative limitations and financial requirements are easier to compare across the two types of benefits, NQTLs are not since they directly relate to the nature of the care provided. This lack of comparability means that, in most cases, the use of any NQTL with respect to mental health or substance abuse care will be suspect. Eliminating this inequity would resolve the issue of systemic lack of comparability between the treatment approaches and settings in the two benefit areas.

To demonstrate this problem, consider that both major depression and diabetes are chronic illnesses and the treatment for both is similar up to a point. The care provider in both cases can prescribe appropriate medication, advocate for certain behavioral or lifestyle changes, and provide appropriate follow-up and evaluation. On-going treatment for diabetes, however, is relatively straightforward. Response to treatment is easy to measure and there is little or no care management involved besides follow-up office visits and laboratory work. By contrast, treatment for depression is more complex and requires on-going management. In addition to the treatment tools noted above for both diabetes and depression, treatment for depression involves the use of psychotherapy, which does not equate with any other type of medical intervention. The psychotherapy process varies based on the practitioner's theoretical orientation (for example, cognitive behavioral, psychodynamic, family systems, etc.) and the presence of factors such life stressors and other conditions that can affect the patient's progress. On-going, concurrent medical management is needed to discuss the treatment process and to ensure that the patient is responding. Without direct consultation with the treating psychiatrist (a process totally absent on the medical side), there is no way to assess the patient's progress. Indeed, it is not unusual to find that a patient diagnosed with

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major depression will, even after six months of seeing a psychotherapist several times a week, show no response to treatment. In such a case, medical management is necessary in order to advocate for addition interventions and/or second opinions.

The different ways in which mental health and substance abuse disorder care and benefits are provided must be respected if patients are to be well-served. Inclusion of NQTLs under the regulations provides a means by which use of these tools will be discouraged. The best way to preserve these salutary differences in approach is to eliminate NQTLs from coverage under the regulations; and,

(e) The Agencies' approach is a detriment to Cenpatico's patients because it deprives MBHOs of the discretion to assure that behavioral health patients receive optimal, cost effective care to the vulnerable population it serves. The Agencies have noted that "[a] shift in source of treatment from primary care physicians to mental health professionals could lead to more appropriate care, and thus, better health outcomes." 75 Fed. Reg. at 5423. Cenpatico agrees with this assessment, but only if the MBHOs are permitted to use their medical necessity criteria and management techniques to determine the best, most cost-effective care. The IFRs, if enforced as is, and finalized without change, would preclude the beneficial outcome the Agencies anticipate. As presently structured, the IFRs accord insurers and benefit managers dealing with medical/surgical care unfettered discretion to develop new structures and different approaches, thereby assuring the most appropriate level and quality of care for their patients. By contrast, the IFRs would have MBHOs and group health plans react to what is done on the medical/surgical area, searching for a comparability of approach rather than concentrating on the needs of the patient.

**4. Revise definitions for mental health and substance abuse disorder benefits**

Cenpatico requests that the definitions of mental health benefits and substance abuse disorder benefits be revised to refer only to the terms of the plan and applicable state laws. The standard adopted by Congress does not permit the interpolation of any standards other than the relevant plan language and applicable Federal and state laws. Those are the only standards that would apply in the case of determination of whether a disorder was medical in nature. To achieve actual parity, the Agencies should allow the same standard to apply to the definitions of mental health and substance abuse disorders and benefits.

**5. Clarify inclusion of drugs for the treatment of mental health or substance abuse disorders**

Cenpatico recommends the Agencies clarify that inclusion of drugs for the treatment of mental health or substance abuse disorders under a prescription drug plan does not constitute the provision of mental health or substance abuse disorder benefits for the purposes of applying the parity requirement. We believe that the six classifications contained in the regulation should be modified so that (1) prescription drug plans and emergency care are included under the parity requirement only when mental health and substance abuse disorders are covered under at least one other classification within the same group health plan and (2) the provision of medical treatment in connection with a mental health or substance abuse disorder will not have the effect of causing the plan to be covered by the parity requirement.

**6. Permit plans to impose either a unified or separate, but no more restrictive deductible**

Since the primary goal of MHPAEA is parity, the best option for achieving this is to permit plans the ability to impose either a unified or no more restrictive deductible. This is the easiest and least invasive way to place both types of benefits on par with each other.

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If the IFR goes into effect without this change, many individuals would have to incur greater out of pocket expenses to access the same care. If unchanged, the IFRs would likely subject the vast majority of plan participants who never require mental health or substance abuse disorder benefits to a higher deductible.

**7. Amend the "Substantially All " Test to Permit Combination of All Types of Cost-Sharing as a Single Financial Requirement.**

As currently drafted, section (c)(3)(i)(A) of the IFRs states that if no single financial requirement applies to "substantially all" (i.e., two-thirds of) medical/surgical benefits, then no financial requirement of the same type may be applied to mental health and substance abuse disorder benefits. Because the regulation further provides for comparison only to the same "type" of financial requirement, co-payments may only be compared to co-payments, deductibles to deductibles, etc. This approach creates the anomalous result that, on the medical/surgical side, all benefits could be subjected to some sort of financial requirement, while no financial requirements at all could be placed on mental health or substance abuse benefits. This would occur, for example, if 55 percent of the medical surgical benefits are the subject of co-payments, and another, different 45 percent to deductibles. In such a case, all of the medical/surgical benefits are the subject of some kind of cost-sharing. However, because no single type of cost sharing applies to two -thirds of the medical surgical benefits, no cost sharing at all would be permitted with respect to mental health and substance abuse disorder benefits.

The Agencies can rectify this by allowing for the combination of all financial requirements in order to determine whether the substantially all standard has been met. Once the standard is met, the plan in question would then be able to satisfy the parity standard by adopting the same limitations for mental health and substance abuse disorder benefits as are applied in the medical/surgical arena. As stated previously in other comments included in this letter, parity entails equality of treatment.

**8. Consider the catastrophic effect the inclusion of NQTLs would have on Medicaid in terms of both cost and quality of care.**

The Centers for Medicare and Medicaid Services (CMS) has stated that, although MHPAEA does not apply directly to Medicare or Medicaid, the standards under MHPAEA will apply in the Medicaid context "insofar as a state's Medicaid agency contracts with one or more managed care organizations (MCOs) or prepaid Inpatient health Plans (PIHPs) to provide medical/surgical benefits as well as mental health or substance abuse disorder benefits . . . ." (CMS Letter to State Health Officials (November 4, 2009) at http://www.cms.hhs.gov/SMDL/downloads/SHO110409.pdf).

For many years, MBHOs like Cenpatico have been engaged under state Medicaid programs to assure the provision of appropriate, cost-effective mental health and substance abuse disorder benefits. These management activities have not only improved the quality of care for this population, but also enabled states to exercise crucial controls on the costs involved in providing this care. These advances have occurred while at the same time there has been little or no management of ambulatory medical/surgical benefits under Medicaid.

Although the IFRs do not apply to Medicaid managed care organizations, Cenpatico believes that there is a significant likelihood that CMS, in adopting regulations for such organizations, will largely rely on the analysis performed by HHS and the other Agencies in issuing the IFRs.

As a result, the inclusion of NQTLs in the IFR will provide a means for undoing all of this progress in realizing cost savings and high quality of care. The absence of medical/surgical ambulatory care management under Medicaid means that employment of managed care techniques for mental health

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or substance abuse disorder Medicaid benefits will be difficult at best under the approach taken in the IFRs.

This highlights the differences between medical/surgical care and mental health and substance abuse disorder treatment in the starkest way possible. The lower income population covered by Medicaid is frequently the population most in need of the types of services provided by MBHOs, especially in terms of treatment design and follow-up. Such services are all implicated by the vague and expansive nature of the NQTLs covered by the IFRs, leading to the likelihood that use of such techniques will be greatly diminished.

The disincentive to use managed care techniques also poses significant cost issues to state Medicaid programs. It is common knowledge that states are currently searching for options to control Medicaid costs in the current economy. As noted above, the application of managed care for mental health under Medicaid has achieved significant cost savings for the states. However, the mandated NQTLs, would include virtually all mental health care management techniques currently in use.

The IFRs, if finalized without change, would negate the states of the ability to control the costs of mental health and substance abuse benefits in any meaningful way. In light of this, and especially because the Agencies have provided no cost estimates as to the effect of including NQTLs in the regulations, Cenpatico urges that the Agencies remove this category from the regulations.

Cenpatico is pleased to have had the opportunity to provide the above comments on the IFRs.

Please feel free to contact me at sdonaldson@centene.com or (512) 406-7200, extension 67515, if you have any questions.

Thank you for consideration of our comments.

Respectfully submitted,

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