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The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

Comment On: CMS-2009-0040-0048

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

Document: CMS-2009-0040-DRAFT-0116

PA

Submitter Information

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General Comment

We appreciate the opportunity to comment on the regulations for the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008.

- We propose that health plans be required to use objective evidence-based assessments of the safety, efficacy, and comparative effectiveness of diagnostic tools and treatments to support conclusions about medical necessity, fail-first and step therapy protocols and standards of care, and in developing coverage policies for mental and behavioral health tests and treatments.
- We propose that health plans be required to use assessments performed by an independent outside party in order to prevent a situation in which plans may circumvent the intent of the law by using internal panels or consultants that are not independent.

Please see also the attached file.

Sincerely,

Elisabeth J. Houtsmuller, Ph.D.

Susan A. Levine, DVM, Ph.D.

Hayes, Inc.

Attachments

CMS-2009-0040-DRAFT-0116.1: PA



Transforming Healthcare with Evidence

May 3, 2010

Centers for Medicare & Medicaid Services
Department of Health and Human Services, Attention: CMS-4140-IFC
File Code: CMS-4140-IFC

Dear Sir or Madam,

We appreciate the opportunity to comment on the regulations for the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008.

Hayes Inc. is an independent health technology research and consulting company that performs unbiased, evidence-based comparative assessments of a wide variety of medical and mental health technologies. Hayes is dedicated to promoting the use of evidence in decision making, policy development, and clinical practice, with the goal of improving health outcomes for all patients. Our worldwide clients include hospitals, healthcare systems, government agencies, employers, and managed care organizations.

Hayes has developed a strong Mental and Behavioral Health division focused on comparative assessments of treatments and diagnostic tools for mental health and substance use disorders. Hayes has evaluated over 50 mental health and substance use disorder treatments and/or diagnostic treatments. These comparative effectiveness assessments are based on a comprehensive and critical review of the best available scientific evidence by a team of analysts with extensive expertise evaluating diagnostic tools and treatments for mental health and substance use disorders.

We are hopeful that the elimination of differences in coverage between mental and substance abuse conditions and medical health conditions will realize Congress' intent to improve patient access to appropriate mental health and substance use disorder services. We wish to comment on the cost containment measures that may be used and the process that should guide them.

Under the new law, cost containment measures such as *medical necessity* criteria, *fail first* policies and *step therapy* protocols can be applied to addiction and mental health benefits as long as they are applied no more stringently than to the plan's medical benefits, except to the extent that *recognized clinically appropriate standards of care* may permit a difference.

The definition of '*medical necessity*' and of specific *fail-first* and *step therapy* policies and the conditions under which these may apply will be key factors in the implementation of the law according to Congress' intent. The process of defining these concepts is complicated by factors such as the controversy regarding the diagnosis of some mental health conditions (e.g., pediatric bipolar disorder) and the availability of multiple treatments for specific conditions (e.g., alcohol addiction, depression). Similarly, '*recognized clinically appropriate standards of care*' is subject to interpretation. The process of defining these concepts should be transparent, objective, consistent, and based on scientific evidence. A specific concern in this respect is that while pharmaceutical treatments are often marketed aggressively to both patients and providers, psychosocial treatments, which can be equally effective for many mental and substance use disorders, are not typically supported by such marketing efforts. Therefore, it is essential that all diagnostic and treatment options be evaluated based on the best available scientific evidence, rather than expert opinion or industry-provided information, which can introduce bias.

- We propose that health plans be required to use objective evidence-based assessments of the safety, efficacy, and comparative effectiveness of diagnostic tools and treatments to support conclusions about medical necessity, fail-first and step therapy protocols and standards of care, and in developing coverage policies for mental and behavioral health tests and treatments.
- We propose that health plans be required to use assessments performed by an independent outside party in order to prevent a situation in which plans may circumvent the intent of the law by using internal panels or consultants that are not independent.

We thank the Departments of Labor, Health and Human Services and Treasury for the opportunity to share our comments and concerns, and hope they are helpful for the successful implementation of this important law. Please let us know if you have any questions or if we can be of further assistance.

Sincerely,

Elisabeth J. Houtsmuller, Ph.D.
Director, Mental and Behavioral Health Programs, Managing Editor

Susan A. Levine, DVM, Ph.D.
Vice President, Health Technology Research and Consulting, Editor-in-Chief

Hayes, Inc.