May 3, 2010

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

Department of Labor
Employee Benefits Security Administration
Office of Health Plan Standards and Compliance Assistance
Room N-5653
200 Constitution Avenue, NW
Washington, DC 20210
Attention: RIN 1210-AB30

Department of Health and Human Services
Centers for Medicare & Medicaid Services
P.O. Box 8016
Baltimore, MD 21244-1850
Attention: CMS-4140-IFC

Department of the Treasury
Internal Revenue Service
Room 5205
P.O Box 7604
Ben Franklin Station
Washington, DC 20044
Attention: CC:PA:LPD:PR (REG-120692-09)

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

Dear Sir or Madam:

Autism Speaks is the nation's largest autism science and advocacy organization, dedicated to funding research, increasing awareness, and advocating on behalf of affected individuals and their families. We write to comment on the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") interim final rules, which were published on February 2, 2010, at volume 75, page 5,410, of the *Federal Register*.

The MHPAEA requires group health plans and health insurance issuers to ensure that the financial requirements and treatment limitations that apply to mental health or substance use disorder benefits are no more restrictive than the predominant requirements or limitations that

apply to substantially all medical and surgical benefits. Autism Speaks urges the departments that have promulgated the interim final rules to use them as a tool to end the discriminatory treatment people with autism have faced in accessing treatment.

I. Executive Summary

Current medical practice recognizes autism as a mental health disorder and benefits for its treatments as mental health benefits. The reported prevalence of autism has risen dramatically in recent years to approximately 1% of the childhood population, along with the burden to individuals, families, and society of providing care. Although effective treatments for autism exist, most insurers refuse to cover them. Many states have responded to the denial of care by enacting laws requiring insurers to provide autism benefits. The departments that have promulgated the interim final rules should affirm that evidence-based treatments for autism fall within the scope of services of the regulations, and should vigorously enforce the rules to prevent treatment limitations that violate mental health parity from denying access to needed care.

II. Autism and Mental Health Parity

A. Autism is Recognized as a Mental Health Disorder

It may be helpful for us to provide some background information on autism and its treatments. Autism is a general term used to describe a group of complex developmental brain disorders. In 1943 Dr. Leo Kanner of the Johns Hopkins Hospital published a groundbreaking paper describing a group of children with impaired communication skills and social interactions and restricted, repetitive behaviors.[1] Kanner used the term "early infantile autism" to refer to the condition. About the same time that Kanner made his observations, an Austrian pediatrician named Hans Asperger published an account of children with an "autistic psychopathy."[2]

The work of Kanner and Asperger helped to establish autism as a distinct condition.[3] In 1980

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[1] Leo Kanner, *Autistic Disturbances of Affective Contact*, 2 Nerv. Child 217 (1943).
[2] Hans Asperger, "*Autistic Psychopathy" in Childhood* (1944) in *Autism and Asperger Syndrome* 37 (Uta Frith trans. & ed., Cambridge University Press 1991).
[3] Autism appears to long predate the studies of Kanner and Asperger:

> *As early as 1867, attention was drawn to mental disorders in young children with severe distortion of the developmental process. Disintegrative psychosis, a condition similar to autism, was first described in 1908. In 1919, Lightner Witmer, considered the father of Clinical Psychology in the United States, described a two-and-a-half-year-old boy, who behaved like an autistic child. In the 1920's, a Russian child psychiatrist described children having characteristics similar to those described by Asperger.*

Vidya Bhushan Gupta, *The History, Definition, and Classification of Pervasive Developmental Disorders*, 33 The Exceptional Parent 58 (2003).

the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) for the first time placed "infantile autism" in a separate diagnostic category. The current DSM, DSM-IV-TR (fourth edition, text revision), identifies five pervasive developmental disorders: autistic disorder; pervasive developmental disorder, not otherwise specified (PDD-NOS); Asperger's syndrome; Rett's syndrome; and childhood disintegrative disorder. DSM-5[4], which is expected to be released in May 2013, subsumes autistic disorder, PDD-NOS, Asperger's syndrome, and childhood disintegrative disorder into a single diagnostic classification, autism spectrum disorder.[5]

The ninth edition of the World Health Organization's International Classification of Diseases, Clinical Modification (ICD-9-CM), classifies pervasive developmental disorders as psychoses. ICD-10-CM, which will replace the current ICD-9-CM diagnosis and procedure codes by October 1, 2013, as the standard for the United States health care industry, categorizes pervasive developmental disorders as disorders of psychological development and lists them in the chapter for mental and behavioral disorders.

B. Autism is Treatable, but Most Health Insurers and Employers Deny or Limit Benefits

However classified, autism is defined by difficulty in reciprocal social interaction and communication and repetition and insistence on sameness. People on the autism spectrum differ. Many, but not all, have language delays. Some, but not all, have lifelong language disorders. Some, but not all, have mental retardation that affects everyday self-care.[6]

Once thought to be rare, autism is now believed to affect about 1 in 110 children in the United States.[7] The dramatic increase in reported prevalence -- 57% in the past two years alone – may be due in part to a true rise in the number of children with the disorder.[8] Autism occurs in all racial, ethnic, and socioeconomic groups, and is 4 to 5 times more likely to occur in boys than in girls. The Centers for Disease Control and Prevention (CDC) estimates that about 730,000

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[4] The fifth edition of the DSM is generally referred to as "DSM-5" rather than "DSM-V."

[5] Unless otherwise indicated, we use the term "autism" to refer to any of the autism spectrum disorders (ASDs).

[6] For an excellent plain language description of the diagnosis and assessment of autism, see Catherine Lord, *Frequently Asked Questions about the Diagnosis of Autism*, http://www.autismspeaks.org/docs/family_services_docs/LORD.Frequently_Asked_Questions_about_Autism_Spectrum_Diagno.pdf (accessed Apr. 7, 2010).

[7] Centers for Disease Control and Prevention, *Prevalence of Autism Spectrum Disorders-Autism and Developmental Disabilities Monitoring Network, United States, 2006,* Morbidity & Mortality Weekly Rep. 58 (SS-10) (Dec.18, 2009).

[8] "No single factor explains the changes in identified ASD prevalence over the time period studied. Although some of the increases are due to better detection, a true increase in risk cannot be ruled out." Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, http://www.cdc.gov/ncbddd/features/counting-autism.html (accessed Apr. 10, 2010).

individuals age 21 and under have autism.[9]

Caring for the large numbers of affected children and adults is as expensive as it is urgent. On average, medical expenditures for individuals with autism are 4 to 6 times greater than for individuals without autism.[10] A 2007 study estimated the lifetime cost of care for an individual with autism to be $3.2 million (about $3.4 million in today's dollars).[11]

Gaps in insurance coverage add to the burdens families bear. In a study of diagnostic exclusions in private behavioral health care plans, researchers examined a total of forty-six commercial, employment-based behavioral health plans covering a total of 496,911 lives. The researchers found that autism was a diagnostic exclusion in *all* of the plans.[12] Underinsurance, or having insurance that does not sufficiently meet one's needs, is a particularly critical issue for children with autism. These children are more likely than other special needs children to delay or forego care entirely.[13] They often suffer from comorbid conditions, such as gastrointestinal disorders, sleep disturbance, seizures, tics, language deficits, anxiety disorders, depression, and attention deficit hyperactivity disorder.[14] Their families have greater out-of-pocket costs, diminished work hours and lost income, and more negative health plan experiences.[15] Many parents of children with autism stop work to care for their child.

Choosing the autism treatment that is right for their child is something all families must do. The CDC identifies these treatment options: behavior and communication approaches; dietary approaches; medication; and complementary and alternative medicine.[16] Government and private entities have developed practice guidelines for specific interventions falling under each of these approaches.[17] There is no single treatment that is best for every child, but some treatments have a stronger evidence base than others.

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[9] Centers for Disease Control and Prevention, Autism Spectrum Disorders (ASDs) Data and Statistics, http://www.cdc.gov/ncbddd/autism/data.html (accessed Apr. 9, 2010).

[10] Tom T. Shimabukuro, Scott D. Grosse & Catherine Rice, *Medical Expenditures for Children with an Autism Spectrum Disorder in a Privately Insured Population*, 38 J. Autism & Dev. Disord. 546 (2008).

[11] Michael L. Ganz, *The Lifetime Distribution of the Incremental Societal Costs of Autism*, 161 Arch. Pediatr. Adolesc. Med., 343 (2007).

[12] Pamela B. Peele, Judith R. Lave &, Kelly J. Kelleher, *Exclusions and Limitations in Children's Behavioral Health Care Coverage*, 53 Psychiatr. Serv. 591 (2002).

[13] Michael D. Kogan et al., *A National Profile of the Health Care Experiences and Family Impact of Autism Spectrum Disorder Among Children in the United States, 2005-2006*, 122 Pediatrics e1149 (2008).

[14] Susan E. Levy, David S. Mandell & Robert T. Schultz, *Autism*, 374 Lancet 1627 (2009); Emily Simonoff et al., *Psychiatric Disorders in Children with Autism Spectrum Disorders: Prevalence, Comorbidity, and Associated Factors in a Population-Derived Sample*, 49 J. Am. Acad. Child Adolesc. Psychiatry 921 (2008) (reporting that 70% of study participants had at least one comorbid psychiatric disorder and 41% had two or more).

[15] Susan H. Busch & Colleen L.Barry, *Does Private Insurance Adequately Protect Families of Children with Mental Health Disorders?,* 124 Pediatrics S399 (2009); Guillermo Montes & Jill S. Halterman, *Association of Childhood Autism Spectrum Disorders and Loss of Family Income*, 121 Pediatrics e821 (2008).

[16] Centers for Disease Control and Prevention, Autism Spectrum Disorders (ASDs) Treatment, http://www.cdc.gov/ncbddd/autism/treatment.html (accessed Apr. 9, 2010).

[17] See, e.g., N.Y. State Dept. of Health Early Intervention Program, *Report of the Recommendations – Autism/Pervasive Developmental Disorders*, available at http://www.health.state.ny.us/community/infants_children/early_intervention/disorders/autism/; National Autism Center, *National Standards Report*, available at http://www.nationalautismcenter.org/pdf/NAC%20NSP%20Report_FIN.pdf.

Among the many treatment methods available, applied behavior analysis (ABA) has become widely accepted among health care professionals as an effective treatment.[18] *Mental Health: A Report of the Surgeon General* states, "Thirty years of research demonstrated the efficacy of applied behavioral methods in reducing inappropriate behavior and in increasing communication, learning, and appropriate social behavior."[19] The seminal research done by Dr. Ivar Lovaas and his colleagues at the University of California, Los Angeles, showed that almost half of all children who receive intensive early intervention are able to achieve normal academic and intellectual functioning.[20] According to the federal Interagency Autism Coordinating Committee, ABA is most effective when used early but can also improve skills in adolescents and adults.[21] The success of ABA translates into a diminished financial burden for both families and the institutions that serve their children.[22]

ABA methods use the following three-step process: an *antecedent*, such as a command or request; a *behavior*, in response to the antecedent; and a *consequence*. The consequence depends on the behavior and can include positive reinforcement, such as praise or a desired object. Success in an ABA program is measured by direct observation and data collection and analysis. ABA treatments typically involve a one-on-one child-therapist interaction and can range in intensity from 25-40 hours per week.

Most health insurers do not cover ABA. In Massachusetts the Division of Health Care Finance and Policy (DHCFP) recently reported the results of a survey with respect to the diagnosis and treatment of autism[23]:

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[18] Behavior analysis is a scientific approach to understanding behavior and how it is affected by the environment. Applied behavior analysis (ABA) is the application of this approach to address socially important problems, and to bring about meaningful behavior change. See Donald M. Baer, Montrose M. Wolf & Todd R. Risley, *Some Current Dimensions of Applied Behavior Analysis,* 1 J. Applied Behavior Analysis 91 (1968). "ABA" is often used to refer both to an approach to treatment and to the treatment itself. Unless otherwise indicated, we use "ABA" to refer to treatment.

[19] U.S. Department of Health and Human Services, "Mental Health: A Report of the Surgeon General" 163-64 (1999).

[20] O. Ivar Lovaas, *Behavioral Treatment and Normal Educational and Intellectual Functioning in Young Autistic Children,* 55 J. Consult. Clin. Psychol. 3 (1987); John McEachin, Tristram Smith, & O. Ivar Lovaas, *Long-Term Outcome for Children with Autism who Received Early Intensive Behavioral Treatment*, 97 Am. J. Ment. Retard. 359 (1993).

[21] Interagency Autism Coordinating Committee, *2010 Strategic Plan for Autism Spectrum Disorder Research* 23 (Jan. 2010), available at http://iacc.hhs.gov/strategic-plan/2010/IACC_2010_Strategic_Plan.pdf.

[22] John W. Jacobson, James A. Mulick & Gina Green, *Cost-Benefit Estimates for Early Intensive Behavioral Intervention for Young Children with Autism – General Model and Single State Case*, 13 Behav. Intervent. 201 (1998); Gregory S. Chasson, Gerald E. Harris & Wendy J. Neely, "Cost Comparison of Early Intensive Behavioral Intervention and Special Education for Children with Autism." 16 *J. Child and Fam. Stud.* 401 (2007); Oliver Wyman Actuarial Consulting, *Actuarial Cost Estimate: Virginia House Bill No. 303 and Senate Bill No. 464* (Jan. 15, 2010), available at http://www.autismvotes.org/atf/cf/%7B2A179B73-96E2-44C3-8816-1B1C0BE5334B%7D/VA%20HB%20303%20and%20SB%20464%20Actuarial%20Cost%20Analysis%201%2015%202010%20Final.pdf (estimating cost savings of legislation requiring coverage of ABA).

[23] Mass. Div. Health Care Fin. & Pol'y, *Review and Evaluation of Proposed Legislation Entitled: An Act Relative to Insurance Coverage for Autism House Bill 3809* 12 (Mar. 2010), available at http://www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/10/mb_autism.pdf.

DHCFP's consultants prepared a survey sent to seven health insurers in Massachusetts. All seven health insurers responded to this survey, including Blue Cross Blue Shield Plans, Fallon Community Health Plan, Harvard Pilgrim Health Care, Neighborhood Health Plan, Tufts Health Plan, Unicare, and United. Health plans also provided additional information, at the request of the consultants, to convey reasons for including, limiting or excluding care that the proposed legislation [a bill to mandate certain autism coverage] would cover. The responses of the health plans were fairly similar. The following statements attempt to generalize the policies of the health insurers and are intended to clarify current health insurance coverage overall with respect to the diagnosis and treatments introduced by H.3809 :

• All but two of the insurers define Autism Spectrum Disorders (ASD) using identical codes, with two of the health plans potentially defining ASD more narrowly.
• All seven insurers indicated that they provide coverage for the diagnosis of ASD, including evaluations and assessments. One of the insurers, however, specifically excludes psychological and neuropsychological testing, because it is considered to be educational in nature. The other insurers might possibly exclude these tests too, but the responses from the other six plans are not sufficiently explanatory to say one way or the other.
• All seven insurers indicated that they do not provide coverage for treatments that are considered habilitative in nature, including ABA. All seven insurers indicated that they exclude ABA because such care is viewed by health plans as habilitative, educational or experimental in nature.
• Psychological and psychiatric services are covered for individuals diagnosed with an ASD in compliance with the Commonwealth's Mental Health Parity Act.
• Pharmacy services are covered for individuals diagnosed with an ASD.
• All seven insurers indicated that they provide therapeutic care, including occupational, speech and physical therapies. Insurers indicated that medical-necessity determinations are based on psychiatric symptoms and the functional impairments that arise from them.

The survey results illustrate the inconsistencies and limits of autism coverage. Although a decade has passed since the Surgeon General's report on mental health, insurers still maintain that the treatment of autism is not medically necessary. After an exhaustive review of the treatment literature, the DHCFP concluded that there is substantial evidence that autism treatments do indeed work:

[W]e think it fair to say that the best-established treatments for autism have shown substantial evidence of efficacy. Skepticism about efficacy and a desire to focus treatment resources on the most effective therapies are useful guides to public discussion and should serve to encourage more efficacy research. From the point of view of parents and care providers who have the most pressing obligation to consider the best interests of children with autism, the evidence now seems strong enough to support substantial provision of therapy as being very

likely in the best interests of the child. We believe that the broader public community of those who may assume some of the financial burden of this care can also regard the evidence as substantial.[24]

Other state review bodies have also rejected the arguments insurers use to deny claims for evidence-based care. Addressing the availability of autism services in Virginia, the Joint Legislative Audit and Review Commission (JLARC) countered the common arguments for denying benefits for autism services:

> *Health insurance companies indicate a number of reasons why they do not provide coverage for certain types of ASD-related services. One reason is that many treatments for ASDs are considered experimental, investigational, or unproven. ABA-based therapy is frequently included in this category, even though medical experts and the AAP [American Academy of Pediatrics] have indicated that sufficient evidence exists to establish its effectiveness. In addition, insurance companies often make a distinction between therapies which are rehabilitative and those which are habilitative, or not restorative, in nature. These definitions often reflect considerations for adults injured or recovering from illness rather than the growth and developmental issues associated with children. Insurance is more likely to cover rehabilitative therapies that restore a level of function. Further, while treatment for medical conditions frequently associated with ASDs, such as digestive problems, are covered under health insurance, other treatments, such as ABA-based techniques, are viewed by health insurers as educational or behavioral and therefore not medically necessary. Medical experts indicate that even though there is often an attempt to classify ASD treatments as either educational or medical, many treatments can be considered both educational and medical so such a distinction is not warranted.*[25]

Faced with a growing demand for autism treatments and an unwavering refusal by health insurance companies to cover those treatments, state legislatures have enacted new laws.

C. Many States Now Require Coverage of Autism Treatment

Over the past decade, nineteen states – eighteen in the last three years -- have passed autism insurance reform measures:[26]

- 2001: Indiana
- 2007: South Carolina; Texas;
- 2008: Arizona; Florida; Louisiana; Pennsylvania; Illinois;
- 2009: New Mexico; Montana; Nevada; Colorado; Connecticut; Texas (expanding scope of prior coverage); Wisconsin; New Jersey;

[24] Id. at 28.
[25] Joint Legis. Audit & Rev. Commission of the Va. Gen. Assembly, *Evaluation of House Bill 83: Mandated Coverage of Autism Spectrum Disorders* 16-17 (2008), available at http://jlarc.virginia.gov/reports/Rpt371.pdf,
[26] For a comprehensive view of state autism insurance laws, see www.autismvotes.org.

- 2010: Maine; Kentucky; Kansas; Iowa.

These bills differ but have common features. All require specified health insurance plans to provide coverage for the diagnosis and treatment of autism. Almost all specify covered treatments; evidence-based treatments such as ABA, speech therapy, occupational therapy, and physical therapy are typical benefits. And almost all have annual or aggregate lifetime dollar limits or age caps, or a combination of limits. The New Jersey Department of Banking and Insurance has concluded that for group health plans subject to MHPAEA, the federal law preempts the state's $36,000 per calendar year limit for ABA-related treatment.[27]

In addition to the states that have enacted legislation, eighteen more states -- Alaska, Delaware, Georgia, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New York, North Carolina, Ohio, Rhode Island, Tennessee, Vermont, Virginia, Washington, and West Virginia, as well as the District of Columbia -- considered or are considering autism insurance bills in the 2010 legislative session.

Mental health parity laws in most states[28] afford additional protections to people with autism. In Vermont, for instance, a health insurance plan must cover treatment of mental health conditions and cannot establish any rate, term, or condition that places a greater financial burden on an insured for access to treatment for a mental health condition than for access to treatment for a physical health condition.[29] The statute defines "mental health condition" as "any condition or disorder involving mental illness . . . that falls under any of the diagnostic categories listed in the mental disorders section of the international classification of disease, as periodically revised." As previously stated, autism is listed in the mental disorders section of ICD-9-CM and ICD-10-CM, so Vermont insurance plans must cover its treatment. Vermont law, however, does not require coverage for any specific treatment. Like Vermont, Maine requires certain insurers to provide benefits for conditions arising from mental illness.[30] The Maine statute specifies pervasive developmental disorders as a category of mental illness. In combination with its very recently enacted autism insurance law, Maine does require coverage of certain treatments, including ABA. Coverage for ABA under Maine's autism insurance law may be limited to $36,000 per year to the extent allowed by federal law. This cap was enacted notwithstanding Maine's mental health parity law, which requires that benefits for the treatment of mental illnesses must be no less extensive than the benefits provided for medical treatment for physical

[27] N.J. Dept. of Banking & Ins. Bulletin 10-02 (Jan. 14, 2010), available at http://www.state.nj.us/dobi/bulletins/blt10_02.pdf

[28] Mental health parity laws in the District of Columbia and at least the following states cover autism: Alabama, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Rhode Island, Vermont, Virginia, and Washington.

[29] Vt. Stat. Ann. tit. 8, § 4089B (2010).

[30] Me. Rev. Stat. Ann. tit. 24 § 2325-A (2010); Me. Rev. Stat. Ann. tit. 24-A § 2843 (2010); Me. Rev. Stat. Ann. tit. 24-A § 4234-A (2010).

illnesses.

Maine is not the only state with both a mental health parity law that covers autism and a separate autism insurance law. The co-occurrence of such statutes highlights a failing: Even the most comprehensive mental health parity statutes have historically not provided mental health benefits even remotely on a par with somatic health benefits, often forcing individuals with autism and their families to go deeply out of pocket for medically necessary treatments.

D. The MHPAEA Interim Rules and Autism Treatment

The MHPAEA interim rules strengthen the protections afforded by state autism insurance and mental health parity laws. The new regulations require plans to use objective benchmarks in classifying a mental health benefit:

> *"Mental health benefits" means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any condition defined by the plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State Guidelines).*[31]

As we have discussed, independent standards of current medical practice recognize autism as a mental health condition, [32] so it should be classified as such under MHPAEA. Benefits with respect to treatments for autism, such as ABA, speech therapy, and medication, should be classified as mental health benefits under MHPAEA.

The legislative history of the MHPAEA provides additional support for placing benefits with respect to autism services under the MHPAEA's protections. During the debate over the legislation, Congressman Frank Pallone, Jr., chair of the Subcommittee on Health of the House Energy and Commerce Committee, and Congressman Bart Stupak expressed concern that health plans would attempt to evade mental health parity by various stratagems, such as misclassifying autism and other conditions. Congressman Pallone stated, "Mental illnesses are biologically based disorders, and there is no reason we should affirmatively provide protections to a student with depression or a young adult with schizophrenia, but not a child with autism . . . ."[33]

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[31] MHPAEA rules, 75 Fed. Reg. 5,409, 5,431, 5,438, 5,445 (Feb. 2, 2010) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 146).
[32] See *supra* notes 1-5 and accompanying text.
[33] 154 Cong. Rec. H1285 (Mar. 5, 2008).

Congressman Pallone's statement recognizes that autism is treatable and that barriers to autism benefits should be eliminated through MHPAEA.

The regulations do not address the scope of services that a group health plan or health insurance coverage must provide to individuals with autism or any other condition. This silence has created confusion. As the prevalence of autism has risen, so has the urgency of addressing the needs of affected individuals and their families. The preamble to the MHPAEA rules notes that "[u]ntreated or under treated mental health conditions and substance use disorders are detrimental to individuals and the entire economy."[34] This is clearly true for autism, with its high unmet health care needs and personal and societal financial burden.[35] The community of affected individuals and their families, as well as state and federal legislators and administrators, service providers, and policymakers who are responding to the public health crisis that autism presents, need the departments that have issued the interim final rules to provide greater clarity as to which services fall within the ambit of the regulations. Autism Speaks urges the departments to require that group health plans provide benefits for any evidence-based treatment.

The regulations do address aggregate lifetime and annual dollar limits as well as financial requirements and treatment limitations, dividing treatment limitations into two categories, quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan. Paragraph (c)(4) of the regulations generally prohibits plans from imposing nonquantitative treatment limitations to mental health benefits:

> *Nonquantitative treatment limitations—(i) General rule. A group health plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in medical surgical/benefits in the classification, except to the extent that recognized clinically appropriate standards of care may permit a difference.*

Nonquantitative treatment limitations explicitly include "[m]edical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative."[36]

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[34] MHPAEA rules at 5,422.
[35] See *supra* notes 10-15 and accompanying text.
[36] MHPAEA rules at 5,436, 5,443, 5,449-50.

The regulations illustrate this limitation by the following example:

> *Example 3. (i) Facts. A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that may differ based on clinically appropriate standards of care for a condition.*
>
> *(ii) Conclusion. In this Example 3, the plan complies with the rules of this paragraph (c)(4) because the nonquantitative treatment limitation—medical appropriateness—is the same for both medical/surgical benefits and mental health and substance use disorder benefits, and the processes for developing the evidentiary standards and the application of them to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if, based on clinically appropriate standards of care, the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.*

The example posits comparability in both developing and applying evidentiary standards – a level playing field, in other words. When it comes to autism benefits, however, the field appears decidedly tilted. DHCFP in Massachusetts and LJARC in Virginia recognized this tilt, concluding that limitations on evidence-based autism services are not justified. Other state review bodies as well as courts have reached this same conclusion.[37]

The fourth example illustrating the rules under paragraph (c)(4) features a plan that applies the same limitation differently for one mental health condition than for other mental health conditions or medical/surgical benefits:

> *Example 4. (i) Facts. A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a black*

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[37] *See, e.g.,* Maine Bureau of Ins., *A Report to the Joint Standing Committee on Insurance and Financial Services of the 124th Maine Legislature* (Dec. 2009, corrected Jan. 14, 2010), available at http://www.state.me.us/pfr/legislative/documents/LD_1198_Autism_Mandate_Final_Report_Corrected.pdf; *McHenry v, PacificSource Health Plans*, 2010 U.S. Dist LEXIS 321 (D. Or. 2010) (rejecting claim that ABA fell under plan exclusions for experimental or investigational procedures or academic and social skills training); *Micheletti v. State Health Benefits Comm'n*, 913 A.2d 842 (N.J. Super. Ct. App. Div.), *sanctions disallowed by, petition granted by*, *Micheletti v. State Health Ben. Comm'n (In re Micheletti)*, 192 N.J. 588 (2007).

box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects). For other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care.

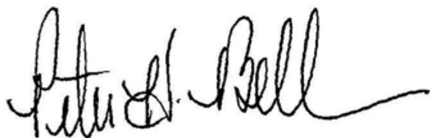
(ii) Conclusion. In this Example 4, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

This example captures the problem that people with autism often face in securing benefits for evidence-based services: the rules are not the same. As applied if not as designed, treatment limitations for autism, such as policies on experimental or investigational services, differ from treatment limitations for other mental health conditions or medical/surgical conditions. The treatment limitations for autism are not based on a fair and balanced review of the best and most recent scientific studies.

Unreasonable treatment limitations make autism services more expensive and less available. We have noted in these comments the high financial and personal cost of autism and the role that underinsurance plays in exacerbating the burdens that families and affected individuals bear. These burdens would be significantly reduced by vigorous enforcement of the MHPAEA. We call on the departments that have promulgated the interim final rules to break down the barriers to autism treatment.

If you have questions about these comments, please contact Stuart Spielman, Senior Policy Advisor and Counsel, at sspielman@autismspeaks.org or (202) 955-3312.

Sincerely,



Peter Bell
Executive Vice President
Programs and Services