

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 Del.C. §512)

PROPOSED

PUBLIC NOTICE

Medical Care and Other Types of Remedial Care - Behavioral Interventions to Treat Autism Spectrum Disorder

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code), 42 CFR §447.205, and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512, Delaware Health and Social Services (DHSS) / Division of Medicaid and Medical Assistance (DMMA) is proposing to amend the Delaware Title XIX Medicaid State Plan regarding Medical Care and Other Types of Remedial Care, specifically, *to establish coverage and reimbursement for treatment services for Medicaid recipients up to age twenty-one (21) years of age who have a diagnosis of Autism Spectrum Disorder.*

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to Kimberly Xavier, by email: Kimberly.xavier@state.de.us, by mail: Planning & Policy Development Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906, or by fax: 302-255-4425 by August 1, 2016. Please identify in the subject line: Behavioral Interventions to Treat Autism Spectrum Disorder.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing to amend the Title XIX Medicaid State Plan regarding Medical Care and Other Types of Remedial Care, specifically, *to establish coverage and reimbursement methodologies for treatment services for Medicaid recipients up to twenty-one (21) years of age who have a diagnosis of Autism Spectrum Disorder.*

Statutory Authority

- §1905 of the Social Security Act (a)(4)(B), *Early and Periodic Screening, Diagnostic, and Treatment Services*
- §1905 of the Social Security Act (a)(6), *Remedial Care and any other type of remedial care (services of other licensed practitioners)*
- §1905 of the Social Security Act (a)(13)(c), *Preventive services*
- §1905 of the Social Security Act (r)(5), *Other necessary health care, diagnostic service, and other measures as described in section 1905(a)*
- 42 CFR §440.60(a), *Medical or other remedial care provided by licensed practitioners*
- 42 CFR §440.130(c), *Diagnostic, screening, preventive, and rehabilitative services*
- 42 CFR §447.205, *Public notice of changes in statewide methods and standards for setting payment rates*

Background

Autism Spectrum Disorder (ASD) is a developmental disorder that can cause significant social, communication, and behavioral challenges. A diagnosis of ASD now includes several conditions that used to be diagnosed separately: autistic disorder, pervasive developmental disorder not otherwise specified (PDD-NOS), and Asperger's syndrome. These conditions are now all called Autism Spectrum Disorder.

Treatments for children with ASD can improve physical and mental development. Generally these treatments can be categorized in four categories: 1) behavioral and communication approaches; 2) dietary approaches; 3) medications; and 4) complementary and alternative medicine.

The federal Medicaid program may reimburse for services to address ASD through a variety of authorities. Services can be reimbursed through section 1905(a) of the Social Security Act (the Act), section 1915(i) state plan Home and Community-Based Services, section 1915(c) Home and Community-Based Services (HCBS) waiver programs, and section 1115 research and demonstration programs.

State Plan Authorities

Under the Medicaid state plan, services to address ASD may be covered under several different section 1905(a) benefit categories. Those categories include: section 1905(a)(6) - services of other licensed practitioners; section

1905(a)(13)(c) - preventive services; and section 1905(a)(10) - therapy services. States electing these services may need to update the Medicaid State Plan in order to ensure federal financial participation (FFP) is available for expenditures for these services. In addition, for children, as discussed below, states must cover services that could otherwise be covered at state option under these categories consistent with the provisions at 1905(a)(4)(B) for Early and Periodic Screening, Diagnostic, and Treatment services (EPSDT). The following information briefly describes these coverage categories for services to address ASD. Under these section 1905(a) benefit categories, all other state Medicaid plan requirements such as state-wideness and comparability must also be met.

1) Other Licensed Practitioner Services

Other Licensed Practitioner services, defined at 42 CFR 440.60(a), are "medical or remedial care or services, other than physicians' services, provided by licensed practitioners within the scope of practice as defined under State law." If a state licenses practitioners who furnish services to address ASD, the state may elect to cover those providers under this section of their state plan even if the providers are not covered under other sections of the plan (e.g., physical therapist, occupational therapist, etc.). A state would need to submit a state plan amendment (SPA) to add the new licensed provider to their Medicaid plan. The SPA must describe the provider's qualifications and include a reimbursement methodology for paying the provider.

2) Preventive Services

Preventive Services, defined at 42 CFR 440.130(c) are "services recommended by a physician or other licensed practitioner of the healing arts within the scope of his practice under state law to--

- Prevent disease, disability, and other health conditions or their progression;
- Prolong life; and
- Promote physical and mental health and efficiency."

A regulatory change that took effect January 1, 2014, permits coverage of preventive services furnished by non-licensed practitioners who meet the qualifications set by the state, to furnish services under this state plan benefit as long as the services are recommended by a physician or other licensed practitioner. Under the preventive services benefit, in the state plan, the state must 1) list the services to be provided to ensure that services meet the definition of preventive services as stated in section 4385 of the State Medicaid Manual (including the requirement for the service to involve direct patient care); 2) identify the type(s) of non-licensed practitioners who may furnish the services; and 3) include a summary of the state's provider qualifications that make these practitioners qualified to furnish the services, including any required education, training, experience, credentialing, supervision, oversight and/ or registration.

3) Therapy Services

Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders, may be covered under the Medicaid therapies benefit at 42 CFR 440.110. Physical and occupational therapy must be prescribed by a physician or other licensed practitioner of the healing arts within the scope of his/her practice under state law and provided to a beneficiary by or under the direction of a qualified therapist. Services for individuals with speech, hearing, and language disorders include diagnostic, screening, preventive, or corrective services provided by or under the direction of a speech pathologist or audiologist, for which a patient is referred by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under state law.

Summary of Proposal

Purpose

Effective July 1, 2016 Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) proposes to adopt provisions to establish coverage and reimbursement methodologies for treatment services for Medicaid recipients up to twenty-one (21) years of age who have a diagnosis of Autism Spectrum Disorder pursuant to 42 CFR §440.60(a) and 42 CFR 440.130(c).

DMMA published a proposed regulation in the April 2016 Delaware *Register*. Due to the extensive comments received, and subsequent changes to the proposed regulation, DMMA has chosen to re-publish this rule as proposed.

The purpose of this proposal is to establish service descriptions, provider qualifications and reimbursement methodologies in the Medicaid State Plan for treatment services for Medicaid recipients up to twenty-one (21) years of age who have a diagnosis of Autism Spectrum Disorder.

Public Notice

In accordance with the *federal* public notice requirements established at Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 447.205 and the state public notice requirements of Title 29, Chapter 101 of the Delaware Code, Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) gives public notice and provides an open comment period for thirty (30) days to allow all stakeholders an opportunity to provide input on the agency's decision to establish coverage and reimbursement for treatment services for Medicaid recipients up to twenty-one (21) years of age who have a diagnosis of Autism Spectrum Disorder. Comments must be received by 4:30 p.m. on August 1,

2016.

CMS Review and Approval

The provisions of this draft state plan amendment (SPA) are subject to the Centers for Medicare and Medicaid Services (CMS) review and approval. The draft SPA page(s) may undergo further revisions before and after submittal to CMS based upon public comment and/or CMS feedback. The final version may be subject to significant change.

Provider Manual Update

Also, upon CMS approval, the applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding manual updates.

Fiscal Impact

The following represents the potential increase in expenditures with the increased level of treatment services for Medicaid recipients up to twenty-one (21) years of age who have a diagnosis of Autism Spectrum Disorder effective July 1, 2016.

The following fiscal impact is projected:

	Federal Fiscal Year 2016 (1)	Federal Fiscal Year 2017
General (State) funds	\$ 301,710	\$ 1,223,105
Federal funds	\$ 450,120	\$ 1,784,218

(1) Represents July – September 2016 only

**DMMA RE-PROPOSED REGULATION #16-015a
REVISION:**

ATTACHMENT 3.1-A
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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: DELAWARE
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PROVIDED TO THE CATEGORICALLY NEEDY

13.c. Preventive Services

In accordance with section 4106 of the Affordable Care Act, Delaware Medicaid Covers and reimburses all preventative services assigned a grade of A or B by the United States Preventive Services Task Force (USPSTF), ~~and~~ all approved vaccines and their administration, recommended by the Advisory Committee on Immunization Practices (ACIP), and behavioral interventions to treat Autism Spectrum Disorder (ASD) without cost-sharing.

Preventative services are any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts acting within the scope of their practice under State law and include all preventative services not otherwise covered under the State Plan pursuant to Section §1905(r)(5) of the Social Security Act, *Early and Periodic Screening, Diagnostic, and Treatment Services*, for other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan. Preventive Services are reimbursed according to the methodologies for services described in Attachment 4.19-B. *Methods and Standards for Establishing Payment Rates – Other Types of Care*, of the State Plan.

The State assures the availability of documentation to support the claiming of federal reimbursement for these preventative services.

The State assures that the benefit package will be updated as changes are made to the USPSTF and ACIP recommendation, and that the State will update the coverage and billing codes to comply with these revisions.

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NEW:

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13.c. Preventive Services Continued

Behavioral Interventions to Treat Autism Spectrum Disorder (ASD) Pursuant to Act, Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services

Covered services are provided in accordance with §1905(a)(4)(B), 1905 (A)(13), and 1905(r) of the Social Security Act. Behavioral interventions to treat Autism Spectrum Disorder (ASD) pursuant to EPSDT are provided only to Medicaid beneficiaries under age twenty-one. Pursuant to 42 C.F.R. § 440.130(c), these services are provided as preventive services and are recommended by a physician or other licensed practitioner of the healing arts within his or her scope of practice under state law to prevent the progression of ASD, prolong life, and promote the physical and mental health and efficiency of the child.

Pursuant to section 4385 of the State Medicaid Manual, preventive services must be direct patient care provided to the child for the primary purpose of diagnosing or treating ASD, which is a set of conditions that directly affects the child's mental and physical health.

Required Evaluation:

Prior to receiving an ASD Assessment or ASD Treatment Services, the child must receive a medical / physical evaluation. This evaluation is a review of the child's overall medical health, hearing, speech, and vision, including relevant information and should include a validated ASD screening tool. The evaluation is designed to rule out medical or behavioral conditions other than ASD so that they can be properly treated, including those that may have behavioral implications and/or may co-occur with ASD. The medical/physical evaluation must be provided by licensed practitioners operating within their scope of practice under state law or regulation, including medical doctors (MD and DO), advanced practice registered nurses (APRN), nurse practitioners, and physician assistants. The medical evaluation may be done at any point prior to a request for ASD services and does not need to immediately precede the request for service.

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13.c. Preventive Services Continued

Behavioral Interventions to treat (ASD) Pursuant to Act, (EPSDT) Services Continued

Autism Spectrum Disorder (ASD) Covered Services

- (1.) ASD Assessments and Support/Treatment Plans

(a.) Functional Behavior Assessment (FBA)

- (1.) Service Description: The FBA attempts to determine the function of maladaptive behaviors subsequent to the diagnosis and to determine appropriate treatment options and recommendations. The FBA is a clinical compilation of observational data, behavior rating scales, and reports from various sources (e.g., the child, schools, family, pediatricians, and other sources) designed to identify the child's current strengths and needs across developmental and behavioral domains. It takes into account all available information, including the medical/physical evaluation and any comprehensive diagnostic evaluations that are available. The FBA should be reviewed no less frequently than every six months or as behaviors or the circumstances of the child change.
- (2.) Assessment Tool: FBA practitioners must use a validated assessment tool or instrument and can include direct observational assessment, observation, record review, data collection and analysis. The FBA must include the current level of functioning of the child using a validated data collection instrument or tool.

(b.) Behavior Support Plan (pursuant to a FBA)

Service Description: Based on the Functional Behavior Assessment, the Behavioral Support Plan is a detailed plan of ASD treatment services specifically tailored to address each child's adaptive and/or behavioral needs. The plan includes at least the following: measurable goals and expected outcomes to determine if ASD treatment services are effective; specific description of the recommended amount, type, frequency, setting and duration of ASD treatment services; and amount and type of recommended caregiver ongoing participation in the ASD treatment services necessary to maximize the success of the services. The service includes skill modeling, feedback, and reinforcement to family members or caregivers based on the Behavior Support Plan to ensure that treatment strategies outlined in the Plan are being transferred and implemented by the family or caregiver. The service is for the direct benefit of the Medicaid recipient.

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13.c. Preventive Services Continued

Behavioral Interventions to treat (ASD) Pursuant to Act, (EPSDT) Services Continued

ASD Covered Services - ASD Assessments and Support/Treatment Plans continued:

(c.) Applied Behavior Analysis (ABA) Assessment

- (1.) Service Description: A developmentally appropriate Applied Behavior Analysis (ABA) Assessment may be performed in lieu of, or in conjunction with, the FBA. An ABA Assessment typically utilizes information obtained from multiple methods and multiple informants, including the following:
- (a.) A file review that includes information about medical status, prior assessment results, response to prior treatment and other relevant information which will be incorporated into the development of treatment goals and intervention.

- (b.) Rating scales and interviews with the child, caregivers, and other stakeholders, as appropriate, are included when selecting treatment goals, developing protocols, and evaluating progress.
 - (c.) Direct observation and data collection and analysis serves as the primary basis for identifying pretreatment levels of functioning, developing and adapting treatment protocols on an ongoing basis, and evaluating response to treatment and progress toward goals. Behavior should be directly observed in a variety of relevant naturally occurring settings and structured interactions.
 - (d.) Periodic assessments from other professionals.
- (d.) ABA Treatment Plan (pursuant to an ABA Assessment)
- (1.) Service Description: Based on the ABA Assessment, the ABA Treatment Plan is a detailed plan that identifies pretreatment levels of functioning, and develops and adapts treatment protocols on an ongoing basis by evaluating response to treatment and progress toward goals. ABA treatment goals are identified based on the previously described ABA Assessment process. Each goal should be defined in a specific, measurable way to allow frequent evaluation of progress toward a specific mastery criterion. The number and complexity of goals should be consistent with the intensity and setting of service provision. The appropriateness of existing and new goals should be considered on a periodic basis. Goals are prioritized based on their implications for the client's health and well-being, the impact on client, family and community safety, and contribution to functional independence.

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13.c. Preventive Services Continued

Behavioral interventions to treat (ASD) Pursuant to Act, (EPSDT) Services Continued

ASD Covered Services Continued

(2.) ASD Treatment Services

- (a.) Service Description: ASD treatment services are interventions designed to treat children with ASD, including a variety of behavioral interventions, which have been identified as evidence-based by nationally recognized research reviews and/or other nationally recognized substantial scientific and clinical evidence. These services are designed to be delivered primarily in the home or in other community settings and include any intervention supported by credible scientific and/or evidence, as appropriate to each child, such as Applied Behavior Analysis (ABA). ABA is the design, implementation, and evaluation of environmental modifications, including the use of direct observation, measurement, and functional analysis of the relationship between the environment and behavior and the use of behavioral stimuli and consequences, to produce socially significant improvement in human behavior.
- (b.) Prohibited practices in the treatment of ASD include:
 - (1.) Aversive interventions;
 - (2.) Seclusion;
 - (3.) Denial of nutritionally adequate diet;
 - (4.) Chemical Restraints;

(5.) Mechanical Restraints; and

(6.) The use of Behavior Modifying Medications without a formal assessment and diagnosis of a corresponding mental health disorder by physician or advance practice nurse.

(c.) ASD Service Delivery: ASD treatment services shall be rendered in accordance with the beneficiary's treatment plan. The treatment plan shall:

(1.) Be person-centered and based upon individualized goals over a specific timeline;

(2.) Be developed by a qualified autism service provider for the specific beneficiary being treated;

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13.c. Preventive Services Continued

Behavioral Interventions to treat (ASD) Pursuant to Act, (EPSDT) Services Continued

ASD Covered Services – ASD Treatment Services Continued

(c.) ASD Service Delivery Continued:

(3.) Delineate both the frequency of baseline behaviors and the treatment planned to address the behaviors;

(4.) Identify long, intermediate, and short-term goals and objectives that are specific, behaviorally defined, measurable, and based upon clinical observation;

(5.) Include outcome measurement assessment criteria that will be used to measure achievement of behavior objectives;

(6.) Utilize evidence-based practices with demonstrated clinical efficacy in treating ASD, that are tailored to the beneficiary;

(7.) Ensure that interventions are consistent with evidenced-based ASD treatment techniques;

(8.) Clearly identify the service type, number of hours of direct service and supervision, and parent or guardian participation, if applicable, needed to achieve the plan's goals and objectives;

(9.) Clearly identify the frequency at which the child's progress is reported;

(10.) Clearly identify the individual providers responsible for delivering the services;

(11.) Include case management to be provided by the ASD service provider involving individuals that are significant in the person's life, school, state disability programs, and others as applicable; and

(12.) Include recommendations for training, support, and participation of the parent/guardian, and other persons chosen by the child as appropriate, to benefit the Medicaid eligible child, as described in the treatment plan. The practitioner must specify the expected level of participation of all caregivers, based on the practitioner's clinical judgment and the child's unique circumstances, as specified in the Behavior Support Plan or ABA Treatment Plan. This participation also acts as training of the caregiver for the benefit of the child and enables the caregiver to be able to reinforce the services for the child in a clinically effective manner.

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13.c. Preventive Services Continued

Behavioral Interventions to treat (ASD) Pursuant to Act. (EPSDT) Services Continued

ASD Covered Services – ASD Treatment Services Continued

(e.) Limitations on ASD Treatment Services: Total ASD treatment services covered under this section and recommended as part of the Behavior Support Plan or ABA Treatment Plan may only be the amount medically necessary for each child. Plans that recommend more than 40 hours per week require prior authorization.

(3.) Qualified Providers:

Autism Spectrum Disorder services must be provided by qualified practitioners, as specified in the section below. Unlicensed practitioners may operate under the supervision of a licensed practitioner that is responsible for the work and work methods, regularly reviews the work performed, and is accountable for the results. Supervision must adhere to the requirements of the practitioner's licensing board and the supervisory relationship must be documented in writing. Qualified practitioners may also be certified by the Behavior Analyst Certification Board (BACB) under one of the categories listed below, and must act within the scope of their certification, as determined by the BACB.

(a.) Licensed Practitioners –

(1.) The following qualified licensed practitioners under Delaware or other State regulation are licensed by a state and may provide ASD services without any other certification: Licensed Clinical Social Workers (LCSWs), Licensed Professional Counselors of Mental Health (LPCMH), advanced practice nurses (APNs), medical doctors (MD and DO), psychiatrists, and psychologists or their assistants. Psychological assistants may only practice under the supervision of a licensed practitioner.

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13.c. Preventive Services Continued

Behavioral Interventions to treat (ASD) Pursuant to Act. (EPSDT) Services Continued

ASD Covered Services – Qualified Providers Continued

(b.) Unlicensed Professionals –

(1.) Unlicensed Professionals must be certified by the Behavior Analyst Certification Board (BACB) under one of the following categories:

(a.) Board Certified Behavior Analyst® (BCBA®)

(b.) Board Certified Assistant Behavior Analyst® (BCaBA®) working under the supervision of a BCBA®

(c.) Registered Behavior Technician working under the supervision of a BCaBA® or BCBA®

(c.) The practitioner who develops the Behavioral Support Plan or Applied Behavior Analysis Treatment Plan should be the same practitioner who performed the Functional Behavior Assessment or Applied Behavior Analysis, except in extenuating circumstances, such as if the practitioner changed employers, moved to another geographic area, or needed to collaborate with another practitioner with different expertise.

Medicaid shall not cover for program services or components of services that are of an unproven, experimental, of a research nature, or that do not relate to the child's diagnosis, symptoms, functional limitations or medical history.

**DMMA RE-PROPOSED REGULATION #16-015c
NEW:**

ATTACHMENT 4.19-B
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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: DELAWARE
METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES –
OTHER TYPES OF CARE

5. Other EPSDT Services Continued

(f) Services to Treat Autism Spectrum Disorder (ASD) Pursuant to EPSDT:

As available, rates are developed using the Resource Based Relative Value Scale (RBRVS) methodology. Rates are established and updated based on the RBRVS methodology as adopted by the Medicare Fee Schedule Data Base.

If no RVU exists, the agency examines the CMS-approved Medicaid fee-for-service rate schedules of other states for similar services that are comparable in program design, program structure and relative costs to Delaware's services. For those services that are substantially similar, another state's fee for the procedure may be adopted.

Except as otherwise noted in the plan, fee schedule rates are the same for both governmental and private providers of these services. Rates are published on the agencies website at the following link:

The fee schedule and any annual periodic adjustments to these rates are published on the Delaware Medical Assistance Program (DMAP) website at: <http://www.dmap.state.de.us/downloads/feeschedules.html>

20 DE Reg. 11 (07/01/16) (Prop.)