



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201

Robert L. Ehrlich, Jr., Governor – Michael S. Steele, Lt. Governor – S. Anthony McCann, Secretary

MARYLAND MEDICAL ASSISTANCE PROGRAM

Waiver for Children with Autism Spectrum Disorder Transmittal No. 4
December 28, 2004

To: Maryland State Department of Education
Waiver for Children with Autism Spectrum Disorder Providers

From: Susan J. Tucker, Executive Director
Office of Health Services

Note: Please ensure that appropriate staff members in your organization are informed of the contents of this transmittal.

Re: Waiver for Children with Autism Spectrum Disorder Proposed Regulations COMAR 10.09.56

Action: Proposed Regulations

Proposed Effective Date: October 1, 2004

Written Comments To:
Michele Phinney
201 W. Preston Street, Room 521
Baltimore, MD 21201
(410) 767-6499

Program Contact Person:
Tia Waddy
Coordinator
Long Term Care and Waiver Services
(410) 767-5220

Comment Period Expires: January 26, 2005

The Maryland Medical Assistance Program proposes to amend Regulations .02, .04-.08, .10, .12, .14 -.16, and .21 and repeal Regulation .13 under COMAR 10.09.56 Waiver for Children with Autism Spectrum Disorder. The amendments, as published in the Maryland Register on December 27, 2004, are attached. The amendments reflect changes to the waiver that became effective October 1, 2004 as determined by the federal Centers for Medicare and Medicaid Services.

The purpose of the proposed amendments is to:

- I. Establish Intensive Individual Support Services and Therapeutic Integration as individual services.
- II. Remove Day Habilitation services, which include regular and intensive levels, as a waiver service.
- III. Modify conditions for eligibility or determining eligibility, as described below:

Medical eligibility

- The licensed psychologist or certified school psychologist who certifies medical eligibility is a member of the multi-disciplinary team and must be employed by the local Infants and Toddlers Program or local school system.

Technical eligibility

- Participants must receive more than 12 hours per week of special education and related services (reduced from 15 hours per week) or
- Participate in an approved Home and Hospital Program.

- IV. Modify qualifications for certain providers of waiver services, as described below:

General Conditions for Participation

- All providers must verify and have available three written references for all individuals who render or delegate services on the provider's behalf.
- All providers must maintain current, signed contracts with all contractors providing waiver services on behalf of the provider.
- All direct care and supervisory staff must obtain criminal background investigations with the exception of environmental accessibility adaptations providers. (This requirement will be effective for new providers on February 1, 2005 and for providers already enrolled in the program on June 1, 2005.)
- Providers or their employees may not have been convicted of or received probation before judgment for any felony or crime that is potentially harmful to participants.
- Providers may request that the Department waive results of criminal history report under certain conditions.
- Providers must maintain and have available written documentation describing waiver services rendered, including dates and hours of services provided to participants for a period of six years.

Intensive Individual Support Services

- The list of individuals qualified to supervise direct care workers has been expanded to include: Licensed professional counselors; Board Certified Behavioral Analysts; or individuals with a Master's or Doctorate in special education or a related field and at least five years experience in providing training or consultation in Autism Spectrum Disorder.

Respite Care Services

- The list of individuals qualified to provide respite care services or supervise direct care workers has been expanded to include: Board Certified Behavioral Analysts; or individuals with a Master's or Doctorate in special education or a related field and at least five years experience in providing training or consultation in Autism Spectrum Disorder.
- Permit facilities that are licensed as Department of Health and Mental Hygiene certified youth camps, and are approved as Autism Waiver providers, to render respite care services.

Supported Employment

- The list of individuals qualified to supervise direct care workers has been expanded to include Licensed professional counselors.

Family Training

- The list of individuals who qualify to be trainers has been expanded to include: Board Certified Behavioral Analysts; or individuals with a Master's or Doctorate in special education or a related field and at least five years experience in providing training or consultation in Autism Spectrum Disorder.

Residential Habilitation Services

- Add specific standards for residential habilitation providers that include the physical plant, providing for more participant choice and integration into a residential community.
 - Facility must have 8 or fewer beds (up to 16 beds with special approval).
- V. Establish documentation standards for Therapeutic Integration and Intensive Individual Support Services, which include written progress notes and individual plans with goals.
- VI. Modify the number of hours a participant may receive Intensive Individual Support Services from 16 hours a day to 30 hours a week.
- VII. Modify the billing unit of Therapeutic Integration services from a daily unit of about four hours to an hourly unit. Providers may bill a minimum of two units and a maximum of four units for this service.

Any questions regarding the content of this transmittal should be directed to Tia Waddy, Coordinator for the Waiver for Children with Autism Spectrum Disorder, at 410-767-5220.

attachment

An individual may hold more than one temporary permit at a time.

D. More than one permit may be issued per year.

[C.]E — [G.]I. (text unchanged)

JOHN D. GREWELL Chairman
Commission of Real Estate Appraisers and
Home Inspectors

Architect Development Program (IDP) training requirement as set forth in this section.

(2) — (5) (text unchanged)

G. (text unchanged)

STEPHEN L. PARKER
Chairman
Board of Architects

Subtitle 21 BOARD OF ARCHITECTS
09.21.01 General Regulations

Authority: Business Occupations and Professions Article, §3-208(a)(1),
Annotated Code of Maryland

Notice of Proposed Action
[04-356-P]

The Board of Architects proposes to amend Regulation .05 under COMAR 09.21.01 General Regulations. This action was considered by the Board of Architects at a public meeting held July 28, 2004, notice of which was given by publication in 31:14 Md. R. 1124 (July 9, 2004), pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to update the date by which the intern development program requirement went into effect to be consistent with the requirements of the National Council of Architectural Registration Boards.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Pamela J. Edwards, Acting Executive Director, Board of Architects, 500 N. Calvert Street, Room 308, Baltimore, MD 21201, or call (410) 230-6263, or fax to (410) 333-0021, or email at pamedwards@dllr.state.md.us. Comments will be accepted through January 31, 2005. No public hearing has been scheduled.

Open Meeting

Final action on the proposed amendments will be considered by the Board of Architects during a public meeting to be held on February 23, 2005, 9:30 a.m., 500 N. Calvert Street, Baltimore, Maryland 21202, pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

.05 Examination.

A. — E. (text unchanged)

F. Intern-Architect Development Program.

(1) Beginning [in June, 1990,] July 1, 1996, and after that, in order for a candidate to take all or any parts of the ARE, the candidate shall have completed the Intern-

Title 10
DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.56 Home and Community-Based Services Waiver for Children with Autism Spectrum Disorder

Authority: Health-General Article, §§2-104(b), 15-103, 15-105, and 15-130,
Annotated Code of Maryland

Notice of Proposed Action
[04-342-P]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .02, .04 — .08, .10, .12, .14 — .16, and .21 and to repeal Regulation .13 under COMAR 10.09.56 Home and Community-Based Services Waiver for Children with Autism Spectrum Disorder.

Statement of Purpose

The purpose of this action is to establish intensive individual support services and therapeutic integration as individual waiver services, amend general and specific conditions for provider participation to ensure greater accountability for services rendered, and require all direct care and supervisory staff to have criminal background investigations. The deletion of day habilitation services as a waiver service is required by the federal Centers for Medicare and Medicaid Services as a condition for continuation of the Autism Waiver. In addition, these amendments make several technical changes to the waiver for children with autism spectrum disorder.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. Federal funds will be lost to local school systems due to the deletion of day habilitation services. Providers will be paid for fewer hours as a result of the reduction of intensive individual support services.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency: Medical Assistance Program	NONE	
B. On other State Agencies: MSDE	(R-) (E-)	\$2,000,000 \$50,879
C. On local governments:	NONE	

	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	\$50,879
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

B. As a result of the federally mandated deletion of day habilitation services, the local school systems throughout the State will lose approximately \$8,000,000 in federal matching funds annually. In addition, according to a service utilization review, approximately 15 participants exceeded the proposed limit of 30 hours per week of intensive individual support services (IISS) by an average of 42 hours per month. At \$26.92 per hour of services, total federal and State expenditures for IISS will be reduced by \$203,515 annually. Fifty percent of the total amount (\$101,758) will be federal funds. The amendments are proposed to become effective April 1, 2005 upon expiration of the period of emergency status. Therefore, the fiscal impact during the remainder of FY2005 is a reduction of \$2,000,000 in federal funds for day habilitation services and a reduced expenditure of \$50,879 in total funds for IISS.

D. The reduction in IISS will result in a loss of revenue of \$50,879 as explained above.

Economic Impact on Small Businesses

The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.

Due to the proposed limitations on IISS, up to 15 providers will lose revenue for this service for a combined total of \$50,879.

Impact on Individuals with Disabilities

The proposed action has an impact on individuals with disabilities as follows:

A reduction in intensive, individual support services may affect approximately 15 children who are currently receiving more than 30 hours of the service per week.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 521, Baltimore, Maryland 21201, or call (410) 767-6499 or 1-877-4MD-DHMH, extension 6499, or fax to (410) 333-7687, or email to regs@dhmh.state.md.us. Comments will be accepted through January 26, 2005.

.02 Participant Eligibility.

A. Medical Eligibility for the Autism Waiver.

(1) To be medically eligible for the services covered under the chapter, an applicant shall be certified by the licensed psychologist or certified school psychologist [on the] who is a member of the participant's multidisciplinary team and is employed by the local Infants and Toddlers Program or local school system, to need ICF-MR level of care, as part of the multidisciplinary team process and using the form for determination of eligibility for level of care in an intermediate care facility for the mentally retarded and persons with related conditions (ICF-MR).

(2) — (3) (text unchanged)

B. Technical Eligibility for the Autism Waiver. An applicant or participant shall be determined by the multidisciplinary team to meet the waiver's technical eligibility criteria if the individual:

(1) — (4) (text unchanged)

(5) If the child has an IEP, receives more than [15] 12 hours per week of special education and related services and requires a more intensive therapeutic program than other students or is currently participating in an approved Home and Hospital Program pursuant to the procedures of COMAR 13A.03.05 and 13A.05.01;

(6) — (9) (text unchanged)

C. — D. (text unchanged)

.04 Conditions for Participation — General.

To provide Autism Waiver services, the provider [shall]:

A. [Be] Shall be approved in accordance with the requirements specified in this chapter;

B. [Have] Shall have a provider agreement in effect, signed with the Program;

C. [Meet] Shall meet all the conditions for participation specified in COMAR 10.09.36, except as otherwise specified in this chapter;

D. [Assure] Shall assure that professional employees who render or delegate services under this chapter have the appropriate experience and health-related license or professional certification to meet the participant's needs;

E. [Assure] Shall assure that direct care workers who render services under this chapter:

(1) — (3) (text unchanged)

F. [Verify] Shall verify the licenses, [or] credentials, and references of all individuals who render or delegate services on the provider's behalf under this chapter, and have a copy of the licenses, [or] credentials, and at least three written references available for inspection;

G. Shall maintain current, signed contracts with all contractors providing waiver services on behalf of the provider that detail the scope of the contractor's responsibility and service documentation;

H. With the exception of environmental accessibility adaptation providers, shall submit to a preemployment criminal background investigation for which the provider applicant or employee of the provider applicant shall:

(1) Submit an application for a criminal history record check to the Criminal Justice Information System Office, Department of Public Safety and Correctional Services;

(2) Direct the Department of Public Safety and Correctional Services to send the criminal history report to the Maryland State Department of Education;

(3) Pay for the criminal history record check; and

(4) Maintain a copy of the criminal history report for all agency employees in the employee's personnel record;

I. May not have been convicted of, received a probation before judgment for, or entered a plea of nolo contendere to a felony or any crime involving mortal turpitude or theft, or have other criminal history that indicates behavior that is potentially harmful to participants;

J. May not hire or retain an employee, on staff or contractually, who is determined through a criminal record history check to have a history of behavior listed in §I of this regulation;

K. Shall have the option to request the Department to waive the provisions of §I of this regulation if the applicant demonstrates that:

(1) The conviction, probation before judgment, or plea of nolo contendere for a felony or any crime involving moral turpitude or theft was entered more than 10 years before the date of the provider application; and

(2) The criminal history does not indicate behavior that is potentially harmful to participants;

[G.] L. [Have] Shall have adequate liability insurance;

[H.] M. [Provide] *Shall provide services in accordance with the requirements of the Autism Waiver plan of care, this chapter, the Autism Waiver, and all relevant federal, State, and local laws and regulations; [and]*

[I.] N. [Agree] *Shall agree to submit claims for payment by the Program for only those services covered under this chapter which have been identified in a participant's Autism Waiver plan of care[.]; and*

O. *Shall agree to maintain and have available written documentation describing waiver services rendered, including dates and hours of services provided to participants, for a period of 6 years, in a manner approved by the Department or its designee.*

.05 Specific Conditions for Participation — Residential Habilitation Services.

To provide the services covered under Regulation .11 of this chapter, the provider agency shall:

A. Provide services in a facility [licensed under] that meets the following requirements:

(1) [COMAR 10.22.08 for community residential services for individuals with developmental disability; or] *Licensed under:*

- (a) *COMAR 10.22.08; or*
(b) *COMAR 01.04.04;*

(2) [COMAR 01.04.04 for residential child care programs;] *Has eight or fewer beds, unless approved by the Maryland State Department of Education to have up to 16 beds due to special needs of children;*

(3) *Has no more than two individuals in a bedroom;*

(4) *Provides opportunities for participants to have personal items in the participant's bedroom that reflect the participant's personal tastes;*

(5) *Provides for input and participation of the participant into eating times, menus, and meal preparation, as appropriate for specific health conditions and in accordance with treatment standards;*

(6) *Provides opportunities for participants to participate in community activities; and*

(7) *Is located and integrated into a residential community.*

B. — O. (text unchanged)

.06 [Specific] Conditions for Participation — [Day Habilitation Services] Intensive Individual Support Services and Therapeutic Integration.

To provide one or more of the services covered under Regulations .12 — .15 of this chapter, the provider agency shall:

A. — C. (text unchanged)

D. Have on site for a [day habilitation or] therapeutic integration services program at least one certified special educator, assistant, or licensed or certified therapist [(counted only for therapeutic integration staffing), who may be a dance, recreation, drama, art, or music therapist()], for every three children, with more staffing as necessary based on participants' needs;

E. (text unchanged)

[F. Demonstrate the necessary staff capacity to provide intensive day habilitation services when needed by participants, including on demand as necessary;]

[G.] F. (text unchanged)

[H.] G. For intensive individual support services, assure supervision of direct care workers by a [licensed psychologist, certified school psychologist, certified special educator, or licensed certified social worker;]:

- (1) *Licensed psychologist;*

(2) *Certified school psychologist;*

(3) *Certified special educator;*

(4) *Licensed social worker;*

(5) *Licensed professional counselor;*

(6) *Board Certified Behavioral Analyst; or*

(7) *Individual with a masters or doctorate degree in special education or a related field and at least 5 years experience in providing training or consultation in Autism Spectrum Disorder.*

[I.] H. Have at least one professional on call at all times for crisis intervention, who:

(1) — (3) (text unchanged)

(4) *Is a licensed physician, licensed psychologist, certified school psychologist, licensed certified social worker, certified special educator, licensed professional counselor, or licensed nurse psychotherapist;*

[J.] I. Demonstrate the capability and capacity of providing Autism Waiver [day habilitation] therapeutic integration, [and] intensive individual support services, or both, by submitting documentation of experience and a written implementation plan which includes policies and procedures;

[K.] J. — [M.] L. (text unchanged)

[N.] M. For initial approval and as a condition of occupancy of any facility used by the program, submit written documentation from responsible approval or licensing authorities verifying that the facility is in compliance with applicable health, fire safety, and zoning regulations; and

[O.] N. For continued approval, maintain written documentation of compliance with applicable health, fire safety, and zoning regulations as a condition of occupancy of any facility used by the program[; and].

[P. For intensive individual support services, assure that direct care workers are supervised by a:

- (1) *Licensed psychologist;*
(2) *Certified school psychologist;*
(3) *Certified special educator; or*
(4) *Licensed certified social worker.]*

.07 Specific Conditions for Participation — Respite Care.

A. — B. (text unchanged)

C. A professional who provides respite care services or supervises a technician rendering the services shall:

(1) Be:

(a) — (b) (text unchanged)

(c) *A qualified developmental disabilities professional in accordance with COMAR 10.09.26.01B(26); [and]*

(d) *Certified nationally by the Behavior Analyst Certification Board as a Board Certified Behavior Analyst; or*
(e) *An individual with a masters degree or doctorate degree in special education or a related field and at least 5 years experience in providing training or consultation in Autism Spectrum Disorder; and*

(2) (text unchanged)

D. (text unchanged)

.08 Specific Conditions for Participation — Family Training.

A. To provide the services covered under Regulation .17 of this chapter, a trainer shall have the appropriate professional experience and credentials to provide the training needed by the participant's family, including:

(1) Be:

(a) (text unchanged)

(b) Licensed as a psychologist, social worker, nurse psychotherapist, speech therapist, professional counselor, marriage and family therapist, or occupational therapist; [and]

(c) *Certified nationally by the Behavior Analyst Certification Board as a Board Certified Behavior Analyst; or*

(d) *Have a masters or doctorate degree from an accredited university in special education or a related field and at least 5 years experience providing training or consulting in Autism Spectrum Disorder; and*

(2) (text unchanged)

B. (text unchanged)

.10 Specific Conditions for Participation — Supported Employment Services.

To provide the services covered under Regulation .19 of this chapter, the provider agency shall:

A. — E. (text unchanged)

F. Designate a certified special educator, qualified mental retardation professional, *licensed professional counselor*, or qualified developmental disabilities professional as the on-site supervisor for the direct care workers;

G. Employ or contract with certain professionals for consultation as needed, who have a health-related license or professional certification as appropriate to meet Autism Waiver participants' needs, such as physician, registered nurse, occupational therapist, physical therapist, licensed certified social worker, psychologist, special educator, *licensed professional counselor*, or speech therapist;

H. Have at least one professional on call at all times for crisis intervention, who:

(1) — (3) (text unchanged)

(4) Is a licensed physician, licensed psychologist, certified school psychologist, licensed [clinical] *certified* social worker, certified special educator, or licensed nurse psychotherapist;

I. — M. (text unchanged)

.12 Covered Services — [Day Habilitation Services] Intensive Individual Support Services and Therapeutic Integration — General.

A. The Program under Regulations .12 — .15 of this chapter does not cover:

(1) Any Medicaid State Plan services which are provided by medical professionals employed by or under contract with the [day] habilitation provider; and

(2) Transportation between a participant's residence and the site for [regular day habilitation services or] therapeutic integration services.

B. The following [three] *two* forms of [day] habilitation are covered:

[(1) Regular or intensive day habilitation services;]

[(2)] (1) — [(3)] (2) (text unchanged)

C. Site of Service.

(1) [Regular day habilitation and therapeutic] *Therapeutic* integration services shall be provided at a nonresidential setting separate from the home or facility where the participant lives.

(2) (text unchanged)

.14 Covered Services — [Day Habilitation Services —] Therapeutic Integration Services.

Therapeutic integration services under this regulation:

A. Are available as a structured after-school or extended day program, lasting [about] *a minimum of 2 hours and a maximum of 4 hours*, for participants identified by the multidisciplinary team as needing these extended hours [in their day habilitation program];

B. — E. (text unchanged)

F. Are not solely educational or recreational in nature, but have a therapeutic rehabilitative orientation, *as evidenced in written progress notes*;

G. — J. (text unchanged)

K. Shall be guided by the participant's Autism Waiver plan of care; [and]

L. *Shall be based on an individualized written plan that identifies goals of the specific therapeutic activities provided; and*

[L.] M. (text unchanged)

.15 Covered Services — [Day Habilitation Services —] Intensive Individual Support Services.

A. Intensive individual support services:

(1) — (8) (text unchanged)

(9) Assist the participant in achieving successful home and community living through structured support, reinforcement, modeling, and behavior management, *as evidenced in written progress notes*;

(10) — (12) (text unchanged)

B. (text unchanged)

C. A licensed psychologist, certified school psychologist, certified special educator, or licensed certified social worker shall be involved to:

(1) — (2) (text unchanged)

(3) Plan and regularly review the participant's therapeutic activities and behavior plans; [and]

(4) Meet regularly with the participant and family and observe the participant in the home setting[.];

(5) *Develop intervention on an individualized basis and identify the interventions on an individualized treatment plan; and*

(6) *Identify in the treatment plan goals and tasks that the intensive individual support services technician is implementing.*

.16 Covered Services — Respite Care.

A. Respite care [shall]:

(1) [Consist] *Shall consist* of intensive, one-on-one interventions with the participant;

(2) [Be] *Shall be* rendered by a qualified:

(a) — (b) (text unchanged)

(3) [Include] *Shall include* services provided to participants who are unable to care for themselves;

(4) [Be] *Shall be* furnished on a short-term basis because of the absence of or need for relief of the participant's family that normally provides the care; [and]

(5) [Be] *Shall be* provided in the participant's home or place of residence, not including a residential habilitation facility[.]; and

(6) *May be provided in a youth camp certified by the Department of Health and Mental Hygiene under COMAR 10.16.06.*

B. (text unchanged)

.21 Limitations.

A. — E. (text unchanged)

F. The Program may reimburse for a participant not more than:

(1) (text unchanged)

[(2)] 12 units per date of service for regular and intensive day habilitation services, combined;]

[(3)] (2) (text unchanged)

[(4)] (3) [One unit] *Four units or less than two units* of therapeutic integration services for a date of service;

[(5)] (4) [16 hours of intensive individual support services for a date of service] 30 hours of intensive individual support services per week;

[(6)] (5) — [(10)] (9) (text unchanged)

S. ANTHONY McCANN
Secretary of Health and Mental Hygiene

Subtitle 10 LABORATORIES

10.10.12 Medical Laboratories — Public Health HIV Testing Programs

Authority: Health-General Article, Annotated Code of Maryland

Regulations	Sections
.01 Scope	17-202
.02 Definitions	17-202
.03 Incorporation by Reference	17-201, 17-202
.04 Public Health Testing License for Rapid HIV Antibody Testing	17-202, 17-204, 17-205, 17-206, 17-207, 17-208, 17-209, 17-210
.05 Quality Assessment Plan and Quality Control Requirements	17-202, 17-206
.06 Personnel Training and Competency	17-202, 17-206
.07 Standard Operating Procedures Manual	17-202
.08 Public Health Testing Program Director	17-203, 17-206
.09 Manufacturer's Requirements	17-202
.10 Confirmatory Test	17-202

Notice of Proposed Action

(04-337-P-I)

The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01 — .10 under a new chapter, **COMAR 10.10.12 Medical Laboratories — Public Health HIV Testing Programs**.

Statement of Purpose

The purpose of this action is to define and set standards for public health testing programs that are associated or affiliated with the Department so that these programs may offer and perform rapid tests for HIV antibodies. This will allow greater access and availability of HIV tests to the general public. The HIV test is performed while the individual being tested waits, and the test results are made available immediately.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

I. Summary of Economic Impact. The standards and requirements in the proposed regulations will have minimal or no economic impact on the regulated industry or issuing agency. Other impacts are minimal or unquantifiable.

II. Types of Economic Impacts.

	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(R+)	Minimal
B. On other State agencies:	NONE	
C. On local governments:	NONE	

Benefit (+) Cost (-)	Magnitude
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- D. On regulated industries or trade groups: (—) Minimal
- E. On other industries or trade groups: NONE
- F. Direct and indirect effects on public: (+) Unquantifiable

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. There will be a minimal increase in licensing revenues for issuing a public health testing permit (license) to perform public health rapid HIV testing.

D. There is a \$50 fee for a 2 year permit to offer or perform public health rapid HIV testing, instead of the customary \$150 or more fee for a permit to operate a laboratory.

F. Individuals in Maryland will have direct access to HIV testing. Individuals that are screened as positive for HIV will be diagnosed more quickly, counseled, and referred to a health care practitioner.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Regulations Coordinator, Department of Health and Mental Hygiene, 201 West Preston Street, Room 521, Baltimore, Maryland 21201, or fax to (410) 337-6687, or email to regs@dnhm.state.md.us, or call (410) 767-6499 or 1-877-4MD-DHMH, extension 6499. These comments must be received by January 26, 2005.

Editor's Note on Incorporation by Reference

Pursuant to State Government Article, §7-207, Annotated Code of Maryland, the CDC "Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test" (January 2003) has been declared a document generally available to the public and appropriate for incorporation by reference. For this reason, it will not be printed in the Maryland Register or the Code of Maryland Regulations (COMAR). Copies of this document are filed in special public depositories located throughout the State. A list of these depositories was published in 31:2 Md. R. 72 (January 23, 2004), and is available online at www.dsd.state.md.us. The document may also be inspected at the office of the Division of State Documents, 16 Francis Street, Annapolis, Maryland 21401.

.01 Scope.

A. This chapter sets the standards and requirements for a person to obtain and maintain a public health testing license to operate a public health testing program to perform rapid HIV antibody testing.

B. This chapter applies to public health testing programs approved by the Secretary to conduct rapid HIV antibody testing.

C. This chapter does not apply to any other type of laboratory testing entity such as a:

- (1) Point-of-care laboratory;
- (2) Commercial reference laboratory;
- (3) Hospital; or
- (4) Physician office laboratory.