
CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal- 158

Date: September 9, 2016

SUBJECT: Revisions to State Operations Manual (SOM) Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities and Exhibit 355, Probes and Procedures for Appendix J

I. SUMMARY OF CHANGES: We are revising the Interpretive Guidance (IG) for Appendix J, Part II–Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities associated with the regulations at §483.460(a)(3) (tag W322), §483.460(a)(3)(ii) (tag W324), §483.460(n)(2) (tag W394) and §483.480(a)(6) (tag W466) as well as §483.460(a)(3)(iv) (tag W327) from Exhibit 355. Since the IGs were released April 27, 2015, it has been brought to our attention that revisions were needed to the IGs at W322 and W324 to remove referenced website links that no longer work. In addition, we have removed all references to website links contained in the guidance and Exhibit 355 in the event that these links become inactive in the future.

NEW/REVISED MATERIAL - EFFECTIVE DATE: September 9, 2016

IMPLEMENTATION: September 9, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix J/Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities/W322/§483.460(a)(3) The facility must provide or obtain preventive and general care
R	Appendix J/Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities/W324/§483.460(a)(3)(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Committee on Immunization Practices of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics;
R	Appendix J/Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities/W394/§483.460(n)(2)/ If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.
R	Appendix J/Part II – Interpretive Guidelines – Responsibilities of Intermediate Care

	Facilities for Individuals with Intellectual Disabilities/W466/§483.480(a)(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.
R	Exhibit 355 –Probes and Procedures for Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities/W327/§483.460(a)(3)(iv)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

W322

(Rev. 158, Issued: 09-09-16, Effective: 09-09-16, Implementation: 09-09-16)

§483.460(a)(3) *The facility must provide or obtain* preventive and general care

Guidance §483.460(a)(3)

The facility has procedures in place to ensure that the clients receive general health care services to assure optimal levels of wellness. General health care services include assessment and treatment of acute and chronic complaints or situations; teaching relevant health care principles to staff and clients; and periodic surveillance of the health status of the clients.

As a result of clinical assessment, referrals are made for specialized assessment and tests. Facility health care staff follow-up to ensure the assessments are done and the findings incorporated into the medical care plan and/or the IPP.

The facility must have arrangements in place to provide routine or episodic laboratory, and radiology services for the clients if not provided in-house or through the clients physician. There must be a written agreement that specifies the responsibilities of the facility and outside provider. (See §483.410(a)).

Preventive health care services include screening procedures designed to identify health concerns and initiate treatment as early as possible. The facility should have a health prevention program in place and follow the plan to address those screenings that the facility will perform periodically that are relevant to all clients, and those screenings associated with a particular gender or age or vulnerability.

Physician refusal to perform a test, such as a pap smear, must be consistent with guidelines for clients, per the local standard in the community.

If the facility has a physician that refuses to provide preventative healthcare based on the client's level of functioning, medical staff at the facility should meet with and consult with this physician in order to ensure that clients receive the same health services as persons living in the local community.

Current recommended screenings for men and women can be accessed at the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Disease Control (CDC).

W324

(Rev. 158, Issued: 09-09-16, Effective: 09-09-16, Implementation: 09-09-16)

§483.460(a)(3)(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Committee on Immunization Practices of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics;

Guidance §483.460(a)(3)(ii)

These immunization guides may be obtained from *the American Academy of Pediatrics and/or the Centers for Disease Control (CDC)*.

W394

(Rev. 158, Issued: 09-09-16, Effective: 09-09-16, Implementation: 09-09-16)

§483.460(n)(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

Guidance §483.460(n)(2)

A facility performing any laboratory service or test must have applied to CMS, and received a Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. An application for a Certificate of Waiver may be made if the facility performs only those tests on the waived list. A complete list of waived tests *can be accessed at the Food and Drug Administration (FDA)*.

If the facility performs any test, not appearing on the waived list, a Certificate of Compliance or Certificate of Accreditation is required. An appropriate CLIA certificate is required regardless of the frequency with which the laboratory services or tests are conducted. When no tests are performed, a CLIA certificate is not needed. Facilities only collecting specimens and not performing testing do not need a certificate.

A not-for-profit, a state, or local government organization may have one certificate covering all the facilities it operates (e.g., all the separately certified residences which fall under its governing body), if no more than a total of 15 types of waived or moderately complex laboratory tests are used. This exception applies only to laboratories performing limited public health testing. See State Operations Manual (SOM) 6008. Each location where a laboratory tests are performed must file a separate application to be separately certified unless the laboratory meets one of the exceptions outlined at 42CFR493.35(b), 493.443(b), or 493.55(b).

Any laboratory located in a state that has a CMS-approved laboratory program is exempt from CLIA certification. Currently there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if the laboratory is located in New York, contact the New York State Agency to determine if the exemption applies.

W466

(Rev.158, Issued: 09-09-16, Effective: 09-09-16, Implementation: 09-09-16)

§483.480(a)(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

Guidance §483.480(a)(6)

The suggested guidelines can be accessed at the United States Department of Agriculture (USDA).

EXHIBIT 355

Probes and Procedures for Appendix J, Part II-Interpretive Guidelines- Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities

(Rev. 158, Issued: 09-09-16, Effective: 09-09-16, Implementation: 09-09-16)

W327 §483.460(a)(3)(iv)

(Rev. 158, Issued: 09-09-16, Effective: 09-09-16, Implementation: 09-09-16)

The current recommendations of the Center for Disease Control and Prevention, **Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities**, (most recent edition) should be followed by the facility. The current guidelines may be accessed at Centers for Disease Control (CDC).