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431.401: Introduction

130 CMR 431.000 establishes the requirements for the provision and reimbursement of independent diagnostic testing facility services under MassHealth. The MassHealth agency pays for independent diagnostic testing facility services that are medically necessary and appropriately provided in accordance with 130 CMR 450.204. All IDTF providers participating in MassHealth must comply with all MassHealth regulations including, but not limited to, 130 CMR 431.000 and 450.000: *Administrative and Billing Regulations*.

431.402: Definitions

The following terms used in 130 CMR 431.000 have the meanings given in 130 CMR 431.402 unless the context clearly requires a different meaning. The reimbursability of services described in 130 CMR 431.000 is not determined by these definitions, but by the application of regulations elsewhere in 130 CMR 431.000 and 450.000: *Administrative and Billing Regulations*.

Direct Supervision — the physician is present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not require that the physician be present in the room when the procedure is performed.

General Supervision — the procedure is furnished under the physician’s overall direction and control, but the physician is not necessarily required during the performance of the procedure.

Independent Diagnostic Testing Facility (IDTF) — a Medicare–certified diagnostic imaging center, freestanding magnetic resonance imaging (MRI) center, portable X-ray provider, sleep center, or mammography van, in a fixed location or mobile entity, that is physically and financially independent of a hospital or physician’s office, and performs diagnostic tests. These tests must be performed by a physician or by licensed, certified nonphysician personnel under appropriate physician supervision and comply with the applicable laws of any state in which it operates.

Interpreting Physician — a physician who determines the meaning of test results provided by the IDTF, either on the IDTF premises or at a remote location.

Mobile IDTF — a facility that takes its equipment to a location other than its own office. The equipment may be small enough to load and unload from a van as with some sonography or PFT equipment; or it may be fixed in the vehicle such as a mobile MRI unit.

Nonphysician Personnel — technicians, employed or contracted by the IDTF, whose function is to perform the technical component of a given diagnostic test.

Personal Supervision — a physician is physically in the room during the performance of the procedure.

Referring Physician — a physician who requests or orders the service but does not necessarily perform the service.

Supervising Physician — a physician responsible for the personal, direct, or general supervision of the testing performed, the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the actions of nonphysician personnel who use the equipment.

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Treating Clinician — a physician (as defined in 42 U.S.C. 1395x(r)) or nurse practitioner, clinical nurse specialist, or physician assistant (as defined in 42 U.S.C. 1395x(s)(2)(K)) who furnishes a consultation or treats a member for a specific medical problem, and who uses the result of a diagnostic test in the management of the member’s specific medical problem.

431.403: Eligible Members

(A) (1) MassHealth Members. The MassHealth agency pays for IDTF services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. 130 CMR 450.105: *Coverage Types* specifically states, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.

(2) Recipients of Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106: *Emergency Aid to Elderly, Disabled and Children Program*.

(B) Member Eligibility and Coverage Type. For information on verifying member eligibility and coverage type, see 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

431.404: Provider Eligibility

The MassHealth agency pays for the services described in 130 CMR 431.000 only when performed by eligible providers of IDTF services who are participating in MassHealth on the date of service. The participating provider is responsible for the quality of all services for which payment is claimed, the accuracy of such claims, and compliance with all regulations applicable to IDTF services under MassHealth. In order to claim payment, the participating provider must be the IDTF that actually performed the service. An IDTF must have one or more supervising physicians who are responsible for the personal, direct, or general supervision of the facility and its personnel in accordance with Medicare requirements at 42 CFR §410.323 (b)(3), the operation and calibration of the equipment, and the quality of the testing performed.

(A) Participating Providers: The following diagnostic testing facilities are eligible to participate in MassHealth as IDTF providers:

- (1) diagnostic imaging centers: centers that perform a variety of tests, including ultrasounds, positron emission tomography (PET) scans, and other imaging studies;
- (2) freestanding MRI centers: independent MRI centers that perform MRI or magnetic resonance angiography (MRA) services in accordance with standards developed by the American College of Radiology (ACR);
- (3) portable X rays: all suppliers of portable X ray services who are in compliance with 42 CFR 486 Part C and are certified under the Medicare program;
- (4) sleep centers: clinics that perform diagnostic tests to determine the existence and type of sleep disorders; and
- (5) mammography vans: mobile facilities that provide radiological tests for breast cancer.

(B) In-State Providers. To be eligible to participate as a MassHealth provider, an IDTF must:

- (1) be located and doing business in the Commonwealth of Massachusetts;
- (2) operate under a clinic license issued by the Massachusetts Department of Public Health, in accordance with regulations at 105 CMR 140.000: *Licensure of Clinics*;

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- (3) when required, obtain a determination of need, issued by the Massachusetts Department of Public Health;
- (4) participate in the Medicare program as an independent diagnostic testing facility; and
- (5) have all radiology equipment used to provide services inspected and certified by the Massachusetts Department of Public Health.

(C) Out-of-State Providers. An out-of-state IDTF provider that does not meet the requirements of 130 CMR 431.404(B)(1), (2), and (3), may participate in MassHealth only if the IDTF is licensed in its own state and it meets the requirements of 130 CMR 431.404(B)(4) and 450.109: *Out-of-State Services*.

431.405: Maximum Allowable Fees

(A) The Massachusetts Executive Office of Health and Human Services (EOHHS) determines the maximum allowable fees for all IDTF services purchased by government agencies. EOHHS publishes a comprehensive listing of IDTF services and rates. Payment is always subject to the conditions, exclusions, and limitations set forth in 130 CMR 431.000. Payment for a service will be the lower of the following:

- (1) the provider's usual and customary fee to the general public for the same or a similar service; or
- (2) the maximum allowable fee listed in the applicable EOHHS fee schedule.

(B) The maximum allowable payment is full compensation for the IDTF service and any related administrative or supervisory duties in connection with the services, regardless of where the service is provided.

431.406: Individual Consideration

(A) Some tests listed in Subchapter 6 of the *Independent Diagnostic Testing Facility Manual* are designated "I.C.," an abbreviation for individual consideration. A fee has not been established for these services. Payment for an individual-consideration service is determined by the MassHealth agency's professional advisers, based on the IDTF's description of the test, which must be included with the claim.

(B) If a service is not listed in Subchapter 6 of the *Independent Diagnostic Testing Facility Manual*, an IDTF may submit a claim by using the appropriate "unlisted service" service code. Payment for an unlisted service is determined by individual consideration, based on the facility's description of the service, which must be included with the claim.

(C) The MassHealth agency considers the following factors when determining the appropriate payment for an individual-consideration service:

- (1) the amount of time required to perform the service;
- (2) the degree of skill required to perform the service;
- (3) the policies, procedures, and practices of other third-party payers;
- (4) the prevailing diagnostic testing ethics and accepted custom of the diagnostic testing community; and
- (5) other standards and criteria as may be adopted by EOHHS or the MassHealth agency.

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431.407: Prior Authorization

(A) The IDTF must obtain prior authorization for services that are designated "P.A." in the service descriptions listed in Subchapter 6 of the *Independent Diagnostic Testing Facility Manual*.

(B) Prior authorization determines only the medical necessity of the authorized service and does not establish or waive any other prerequisites for payment such as member eligibility or resort to health insurance payment.

(C) All requests for prior authorization must be submitted in accordance with the instructions found in Subchapter 5 of the *Independent Diagnostic Testing Facility Manual*. No payment will be made for such services unless prior authorization has been obtained from the MassHealth agency before the delivery of service. The MassHealth agency will not grant retroactive prior-authorization requests.

431.408: Separate Procedures

Certain procedures are designated "S.P." in the service descriptions in Subchapter 6 of the *Independent Diagnostic Testing Facility Manual*. "S.P." is an abbreviation for separate procedure. A separate procedure is one that is commonly part of a total service and therefore does not generally warrant a separate fee, but will be paid separately if the other portions of the service are not performed.

431.409: Ordering of Tests

The member's treating clinician must order all diagnostic tests. The supervising physician for the IDTF, whether or not for a mobile unit, may not order tests to be performed by the IDTF, unless the supervising physician is the member's treating physician and is not otherwise prohibited from referring to the IDTF. The supervising physician is the member's treating physician if he or she furnishes a consultation or treats the member for a specific medical problem and uses the test results in the management of the member's medical problem.

(A) Order Requirements.

(1) a testing facility that furnishes a diagnostic test ordered by the treating clinician may not change the diagnostic test or perform an additional diagnostic test without a new order.

(2) an order is a communication from the treating clinician requesting that a diagnostic test be performed for a member. The order may conditionally request an additional diagnostic test for a particular member if the result of the initial diagnostic test ordered yields to a certain value determined by the treating clinician (e.g., if test X is negative, then perform test Y). An order may include the following forms of communication:

(a) a written document signed by the treating clinician, which is hand-delivered, mailed, or faxed to the testing facility; or

(b) a telephone call by the treating clinician to the testing facility.

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(B) If the order is communicated via telephone or electronic message, the treating clinician and the testing facility must document the telephone call or electronic message in their respective copies of the member's medical records.

431.410: Payment

(A) Global Fee. Payment for a diagnostic procedure performed at an IDTF will include facility costs, technical costs, and professional costs.

(B) Terminated Procedures. Upon review, the MassHealth agency may pay for procedures that were unable to be completed after the procedure was initiated.

431.411: Service Descriptions and Limitations: Levels of Physician Supervision

Independent diagnostic testing facilities must provide the appropriate level of physician supervision for each procedure in accordance with Medicare requirements at 42 CFR §410.323 (b)(3). The definition of each level of physician supervision is set forth in 130 CMR 431.402.

431.412: Service Descriptions and Limitations: Sleep Centers

(A) Sleep centers enrolled as IDTFs may bill for at-home pulse oximetry services. The MassHealth agency will pay only for pulse oximetry tests and polysomnography used to determine sleep disorders.

(B) For sleep testing to be performed in an IDTF, the supervising physician must be certified by boards in psychiatry and neurology, internal medicine with pulmonary specialty, or in sleep medicine. IDTF technologists must be certified in electroneurodiagnostic testing or registered in polysomnography.

431.413: Covered Services

The MassHealth agency pays for IDTF services necessary for the diagnosis, detection, and treatment of disease, and for the maintenance of the health of MassHealth members, subject to all restrictions and limitations described in MassHealth regulations at 130 CMR 431.000 and 450.000.

431.414: Noncovered Services

The MassHealth agency does not pay for the following services:

(A) tests performed for experimental or investigational purposes, or that are themselves experimental or investigational; and

(B) tests performed for forensic purposes or any purpose other than those described in 130 CMR 431.413, including but not limited to:

- (1) tests performed to establish paternity; and
- (2) post-mortem examinations

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431.415: Recordkeeping Requirements

(A) The IDTF is responsible for ensuring the medical necessity of the tests and maintaining test results in the member's health record.

(B) IDTFs must maintain a medical-record system promoting quality and confidential member care in accordance with Massachusetts Department of Public Health regulations at 105 CMR 140.000: *Licensure of Clinics*. This system must collect and retain data in a comprehensive and efficient manner and permit the prompt retrieval of information. Accurate and complete medical records must be maintained for each member receiving testing services from the IDTF. The data maintained in the member's medical record must also be sufficient to justify any further diagnostic procedures. The medical record must be clear and legible, and readily accessible to health-care practitioners and the MassHealth agency. The medical record must be maintained by the IDTF for at least six years.

(C) The medical record must contain, at a minimum, the following information:

- (1) the member's name, address, telephone number, date of birth, and MassHealth identification number;
- (2) the date of service;
- (3) the name, title and signature of the referring clinician;
- (4) a written order for the tests to be performed;
- (5) the name, title, and signature of the person performing the service;
- (6) the name of the supervising physician;
- (7) pertinent findings on examination; and
- (8) tests performed and results.

REGULATORY AUTHORITY

130 CMR 431.000: M.G.L. c. 118E, §§. 7 and 12