



Commonwealth of Massachusetts
Executive Office of Health and Human Services
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MASSHEALTH
TRANSMITTAL LETTER CHC-72
December 2004

TO: Community Health Centers Participating in MassHealth
FROM: Beth Waldman, Medicaid Director *BW*
RE: *Community Health Center Manual* (Revised Pharmacy Services Regulations)

This letter transmits revisions to the community health center regulations about prescription drugs. These revisions describe the MassHealth 340B drug-pricing program for drugs obtained in accordance with Section 340B of Public Health Law 102-585.

These regulations are effective January 1, 2005.

If you have any questions, please call MassHealth Provider Services at 617-628-4141 or 1-800-325-5231.

NEW MATERIAL

(The pages listed here contain new or revised language.)

Community Health Center Manual

Pages iv-a, 4-1 through 4-4, and 4-23 through 4-28

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Community Health Center Manual

Pages iv-a, 4-1 through 4-4, 4-23, and 4-24 — transmitted by Transmittal Letter CHC-57

Pages 4-25 and 4-26 — transmitted by Transmittal Letter CHC-70

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405.401: Introduction

All community health centers participating in MassHealth must comply with the regulations governing MassHealth, including but not limited to 130 CMR 405.000 and 130 CMR 450.000.

405.402: Definitions

The following terms used in 130 CMR 405.000 have the meanings given in 130 CMR 405.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 405.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 405.000 and in 130 CMR 450.000.

340B Covered Entities – facilities and programs eligible to purchase discounted drugs through a program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992.

340B Drug-Pricing Program – a program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992, permitting certain grantees of federal agencies access to reduced cost drugs for their patients.

Family Practitioner — a licensed physician who is board-eligible or board-certified in family practice. A family practitioner provides continuous, accessible medical care with emphasis on the family unit that combines appreciation of both the biomedical and psychosocial dimensions of illness. The family practitioner assumes responsibility for and provides most of the member’s health care, and coordinates the member’s total health needs.

Freestanding Clinic — any institution licensed as a clinic by the Massachusetts Department of Public Health pursuant to M.G.L. c. 111, s. 51 that is not part of a hospital and that possesses its own legal identity, maintains its own patient records, and administers its own budget and personnel. Such institutions include community health centers and mental health centers.

Group Clinic Visit — a session conducted by a physician, physician assistant, nurse practitioner, or registered nurse to introduce preventive medicine approaches to personal health and safety and to present self-help and personal management information concerning family medicine, adult medicine, sex education, and chronic illness.

Health Practitioner — an individual who can diagnose and treat medical problems whether by authority of his or her own license or by the delegated authority of a licensed medical professional.

HIV Pre-Test Counseling Visit — a face-to-face meeting at the CHC between the member and a physician, physician assistant, nurse practitioner, registered nurse, or counselor (working under the supervision of one of the aforementioned) for the purpose of providing counseling before HIV testing. Providers will offer information on risk factors and implications of both positive and negative test results, in accordance with established protocols of the Massachusetts Department of Public Health.

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HIV Post-Test Counseling Visit — a face-to-face meeting at the CHC between the member and a physician, physician assistant, nurse practitioner, registered nurse, or counselor (working under the supervision of one of the aforementioned) for the purpose of providing counseling after HIV testing. Such counseling will include information about the implications of positive and negative test results, risk-reduction techniques, partner notification, and referral to medical and support services, in accordance with established protocols of the Massachusetts Department of Public Health.

Home Visit — a face-to-face meeting between a member and a physician, physician assistant, nurse practitioner, or registered nurse in the member's residence for examination, diagnosis, or treatment.

Hospital Visit — a face-to-face meeting between a member and a physician, physician assistant, nurse practitioner, or registered nurse when the member has been admitted to a hospital by a physician on the CHC's staff.

Individual Medical Visit — a face-to-face meeting at the CHC between a member and a physician, physician assistant, nurse practitioner, or registered nurse for medical examination, diagnosis, or treatment.

Individual Mental Health Visit — a face-to-face meeting at the CHC between a member and a psychiatrist for mental health examination and diagnosis.

Institutionalized Individual — for purposes of 130 CMR 405.428 through 405.430, an individual who is:

- (1) involuntarily confined or detained, under a civil or criminal statute in a correctional or rehabilitative facility, including a psychiatric hospital or other facility for the care and treatment of mental illness; or
- (2) confined, under a voluntary commitment, in a psychiatric hospital or other facility for the care and treatment of mental illness.

Mentally Incompetent Individual — for purposes of 130 CMR 405.428 through 405.430, an individual who has been declared mentally incompetent by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes that include the ability to consent to sterilization.

Nursing Facility Visit — a visit by a physician, physician assistant, nurse practitioner, or registered nurse to a member who has been admitted to a nursing facility, extended care facility, or convalescent or rest home.

Primary or Elective Care — medical care required by individuals or families that is appropriate for the maintenance of health and the prevention of illness. This care includes but is not limited to physical examination, diagnosis and management of illness, ongoing health maintenance, accident prevention, and referral when necessary. This care does not require the specialized resources of a hospital emergency department.

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Sterilization — any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing. A sterilization is “nontherapeutic” when the individual has chosen sterilization as a permanent method of contraception. A sterilization is “therapeutic” when it occurs as a necessary part of the treatment of an existing illness or injury or is medically indicated and performed in conjunction with surgery upon the genito-urinary tract.

Urgent Care — medical services required promptly to prevent impairment of health due to symptoms that a prudent lay person would believe require medical attention, but are not life-threatening and do not pose a high risk of permanent damage to an individual’s health. Urgent care does not include elective or primary care.

405.403: Eligible Members

- (A) (1) MassHealth Members. MassHealth covers community health center services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. 130 CMR 450.105 specifically states, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.
- (2) Recipients of the 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.

(B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

405.404: Provider Eligibility

Payment for the services described in 130 CMR 405.000 will be made only to providers of community health center services who are participating in MassHealth on the date of service.

(A) In State. To participate in MassHealth, a CHC located in Massachusetts must meet the qualifications for certification or provisional certification in 130 CMR 405.405.

(B) Out of State. To participate in MassHealth, an out-of-state community health center must obtain a MassHealth provider number and meet the following criteria:

- (1) if the center is required by its own state's law to be licensed, the center must be licensed by the appropriate state agency under whose jurisdiction it operates;
- (2) the center must participate in its state's medical assistance program (or the equivalent); and
- (3) the center must have a rate of payment established by the appropriate rate setting regulatory body of its state.

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405.405: Certification

(A) Application. An application for certification as a CHC must be made on the form provided by MassHealth and must be submitted to MassHealth's Program Specialist for community health centers. Upon receipt of the completed application, the Program Specialist or his or her designee may arrange a site visit with the applicant to determine compliance with 130 CMR 405.406 through 405.416 inclusive, and if the applicant offers one or more of the services described in 130 CMR 405.431 through 405.471, compliance with the applicable portions of those sections. Based on the information revealed by the application and the site visit, MassHealth will determine whether the applicant is certifiable, provisionally certifiable, or not certifiable. The Program Specialist will promptly notify the applicant of the determination in writing. If the applicant is not certifiable, the notice will contain a statement of the reasons for that determination.

(B) Certification. A determination of certifiability indicates that the applicant has been found by MassHealth to be in compliance with 130 CMR 405.406 through 405.416 inclusive and, to the extent applicable, with 130 CMR 405.431 through 405.471. Upon such determination of certifiability, the CHC may enter into a provider agreement with MassHealth in accordance with MassHealth regulations in 130 CMR 450.000.

(C) Provisional Certification. Provisional certification means that MassHealth has determined the applicant to be in compliance with the sections referred to in 130 CMR 405.405(B) above except for one or more of the following: 130 CMR 405.408(F) (Nutrition Services), 130 CMR 405.408(C) (Obstetrics/Gynecology), 130 CMR 405.414 (Translation Services), or 130 CMR 405.415 (Emergency Backup Services). If an applicant has been provisionally certified, the letter of notification will specify the certification requirements with which the applicant has failed to comply and the schedule for achieving compliance. When requirements for full certification have been met, MassHealth will certify the CHC. Upon notice of provisional certification, the CHC may enter into a provider agreement with MassHealth in accordance with MassHealth regulations in 130 CMR 450.000, on the condition that such provider agreement, by its own terms, will expire upon the date fixed in the letter of notification for full compliance.

(D) Review of Certification.

(1) MassHealth's Program Specialist for community health centers has the right to review a certified or provisionally certified provider's continued compliance with the conditions for certification referred to in 130 CMR 405.405(A), (B), and (C) upon reasonable notice and at any reasonable time during the hours of operation of the provider. The Program Specialist has the right to revoke the certification or provisional certification of a provider, subject to any applicable provisions of MassHealth regulations in 130 CMR 450.000, if such review reveals that the provider has failed or ceased to meet such conditions.

(2) Any changes in the manager or professional services director or in the scope of services provided by a CHC must be reported in writing to MassHealth's Program Specialist for community health centers. Any additions to the scope of services must be approved in writing by the Program Specialist before they are reimbursable by MassHealth. Deletions of services may result in review of the CHC by MassHealth to determine whether the CHC still meets the requirements for certification set forth in 130 CMR 405.405.

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405.451: Electrocardiogram (EKG) Services: Introduction

MassHealth will pay for an electrocardiogram (EKG) service, only when the service is provided at the written request of a CHC staff physician who will interpret or review the interpretation of the EKG. Documentation of the physician's request must be kept in the member's medical record.

405.452: Electrocardiogram (EKG) Services: Eligibility to Provide Services

A CHC may claim payment for electrocardiogram (EKG) services only when both of the following conditions are met.

- (A) The CHC owns or rents its own EKG equipment.
- (B) The EKG is taken at the CHC or at the member's home.

405.453: Electrocardiogram (EKG) Services: Payment Limitations

(A) The maximum allowable fees include payment for both the technical and professional components of the service. The test must be performed at the CHC and interpreted by a physician employed by the CHC.

(B) A CHC must not bill for a visit when a member is being seen for an EKG only.

(130 CMR 405.454 through 405.460 Reserved)

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405.461: Audiology Services: Introduction

In order for a CHC to be paid for an audiology service other than a hearing test performed as part of an EPSDT services assessment (see 130 CMR 450.140 through 450.149), a written request must be made by a physician, nurse practitioner, or physician assistant who has found some indication of a hearing problem. Documentation of the request and of the hearing problem must be kept in the member's medical record.

405.462: Audiology Services: Eligibility to Provide Services

(A) A CHC may claim payment for a basic pure-tone (air and bone) evaluation by audiometer furnished to a member only when the following conditions are met.

- (1) The CHC possesses on its premises a pure-tone audiometer, which must be calibrated at least once every six months. Records of calibrations must be kept and made available to MassHealth upon request. The machine must be placed and testing conducted in a quiet room.
- (2) The person conducting hearing evaluations is trained to perform hearing tests with an audiometer.
- (3) The quality of the tester's work is assessed at least twice a year by an audiologist certified by the American Speech, Language, and Hearing Association (ASLHA) in accordance with ASLHA standards. The audiologist may be a consultant to the CHC.

(B) A CHC may claim payment for conducting acoustic impedance testing only when the following conditions are met.

- (1) The test is conducted by an ASLHA-certified audiologist on the premises of the CHC.
- (2) The test is conducted by means of a functioning impedance bridge that is placed in a quiet room.

(C) If a problem or abnormality is detected or believed to be present after completion of either the basic pure-tone evaluation or the acoustic impedance test or both, the member must be referred to an otologist or an otolaryngologist for a more complete audiological evaluation and treatment as necessary.

405.463: Audiology Services: Payment Limitations

(A) Audiology services that are not listed in Subchapter 6 of the *Community Health Center Manual* are not reimbursable when furnished in a CHC.

(B) A CHC must not bill for a visit when a member is seen for audiology services only.

(130 CMR 405.464 and 405.465 Reserved)

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405.466: Pharmacy Services: Participation in the 340B Drug-Pricing Program for Outpatient CHC Pharmacies

(A) Notification of Participation. A CHC that is a 340B-covered entity may provide drugs to MassHealth members through the 340B drug-pricing program provided that it notifies MassHealth by submitting to MassHealth a copy of the form used to register with the Health Resources and Services Administration, Office of Pharmacy Affairs (OPA), as a 340B-covered entity and, if applicable, a copy of the OPA form used to certify the contracted pharmacy services. The CHC may provide and bill for 340B drugs to MassHealth members, provided directly or through a subcontract, after MassHealth confirms, in writing, its receipt of the CHC's notification and copy of its OPA registration form, in accordance with 130 CMR 405.466(A).

(B) Subcontracting for 340B Outpatient CHC Pharmacy Services.

(1) A CHC that is a 340B-covered entity may contract with a MassHealth pharmacy provider to dispense 340B drugs for the 340B-covered entity's MassHealth patients. All such subcontracts between the 340B-covered entity and a pharmacy provider must be in writing, ensure continuity of care, specify that the CHC pays the pharmacy, specify that such payment constitutes payment in full for 340B drugs provided to MassHealth members, be consistent with all applicable provisions of 130 CMR 406.000, and are subject to MassHealth approval. The 340B-covered entity must comply with the requirements of 130 CMR 405.466(A) by submitting to MassHealth a copy of the form used to register with the Health Resources and Services Administration, Office of Pharmacy Affairs (OPA), as a 340B-covered entity and a copy of the OPA form used to certify the contracted pharmacy services for the 340B drug-pricing program.

(2) The CHC is legally responsible to MassHealth for the performance of any subcontractor. The CHC must ensure that every pharmacy subcontractor is licensed by the Massachusetts Board of Registration in Pharmacy, is a MassHealth pharmacy provider, and that services are furnished in accordance with MassHealth pharmacy regulations at 130 CMR 406.000 and all other applicable MassHealth requirements, including but not limited to, those set forth in 130 CMR 450.000.

(C) Termination or Changes in 340B Drug-Pricing Program Participation. A CHC must provide MassHealth 30 days' advance written notice of its intent to discontinue, or change in any way material to MassHealth, the manner in which it provides 340B outpatient drugs for its MassHealth patients.

(D) Payment for 340B Outpatient CHC Pharmacy Services. MassHealth pays the 340B-covered entity for outpatient CHC pharmacy services, whether provided and billed directly or through a subcontractor, at the rates established in DHCFFP regulations at 114.3 CMR 31.00.

(130 CMR 405.467 through 405.470 Reserved)

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405.471: Optional Reimbursable Services

A CHC may elect to provide the following services on site or by referral, but it is not required to do so under 130 CMR 405.000. The CHC must notify MassHealth in writing of each service listed in 130 CMR 405.471(A) through (F) that the CHC will provide on site. All services provided on site must be provided and payment claimed in compliance with the applicable MassHealth regulations for each service, including applicable fee schedules. Services the CHC may elect to provide include:

- (A) adult day health services;
- (B) adult foster care;
- (C) day habilitation;
- (D) family planning;
- (E) psychiatric day treatment; and
- (F) speech and hearing services as described in 130 CMR 413.000.

(130 CMR 405.472 through 405.495 Reserved)

405.496: Utilization Management Program

MassHealth pays for procedures and hospital stays that are subject to the Utilization Management Program only if the applicable requirements of the program as described in 130 CMR 450.207 through 450.211 are satisfied. Appendix E of the *Community Health Center Manual* contains the name, address, and telephone number of the contact organization for the screening program and describes the information that must be provided as part of the review process.

REGULATORY AUTHORITY

130 CMR 405.000: M.G.L. c. 118E, §§ 7 and 12.