Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
www.mass.gov/masshealth

MassHealth
Transmittal Letter CHC-117
January 2022

TO: Community Health Centers Participating in MassHealth

FROM: Amanda Cassel Kraft, Assistant Secretary for MassHealth

RE: *Community Health Center Manual* Revised Regulations at 130 CMR 405.000

This letter transmits revisions to the community health center (CHC) regulations at 130 CMR 405.000 to conform to changes made in the pharmacy regulations at 130 CMR 406.000.

Pharmacy Services: Participation in the 340B Drug-Pricing Program for outpatient CHC pharmacies was amended (see 130 CMR 405.466(A)) to give MassHealth the authority to exclude certain drugs from purchase through the 340B Drug-Pricing Program for MassHealth members. This authority applies to drugs that cost more than $100,000 per year gross cost per utilizer (as defined in 130 CMR 406.402) and is limited to no more than 25 drugs. MassHealth will provide notice of its intention to exclude drugs from purchase through the 340B drug pricing program consistent with requirements of M.G.L. c. 118E, §13L and allow for provider input.

These regulations are effective January 24, 2022.

MassHealth Website

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Questions

If you have any questions about the information in this transmittal letter, please contact the MassHealth Customer Service Center at (800) 841-2900, email your inquiry to providersupport@mahealth.net, or fax your inquiry to (617) 988-8974.

NEW MATERIAL

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

Community Health Center Manual

Pages iv, iv-a, 4-1, 4-2, and 4-27 through 4-30

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Community Health Center Manual

Pages iv, 4-1, 4-2, and 4-27 through 4-30 — transmitted by Transmittal Letter CHC-112

4. Program Regulations

130 CMR 405.000: *Community Health Center Services*

4. Program Regulations (cont.)

130 CMR 405.000: *Community Health Center Services*

405.401: Introduction

All community health centers (CHCs) participating in MassHealth must comply with the regulations governing MassHealth, including but not limited to 130 CMR 405.000 and 130 CMR 450.000: *Administrative and Billing Regulations*.

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 130 CMR 405.000 and 450.000: *Administrative and Billing Regulations*.

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

340B Drug Pricing Program — a program established by Section 340B of Public Law 102-585, the Veterans Health Act of 1992.

Acupuncture — the insertion of metal needles through the skin at certain points on the body, with or without the use of herbs, with or without the application of an electric current, and with or without the application of heat to the needles, skin, or both.

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.

Family Therapy — a session for simultaneous treatment of two or more members of a family.

Freestanding Clinic — any institution licensed as a clinic by the Massachusetts Department of Public Health pursuant to M.G.L. c. 111, § 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 CHCs and mental health centers.

Gross Cost Per Utilizer Per Year – annual cost per utilizer projected by EOHHS based on factors including actual or expected utilization, dosing information, duration of therapy, and the National Average Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC) (when NADAC is not available) of the covered drug prior to any federal or supplemental rebate.

Group Clinic Visit — a session conducted by a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, 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. Tobacco cessation group clinic visits may be provided by MassHealth-qualified tobacco cessation counseling providers as defined in 130 CMR 405.472.

Group Therapy — application of psychotherapeutic or counseling techniques to a group of persons, most of whom are not related by blood, marriage, or legal guardianship.

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 Post-test Counseling Visit — a face-to-face meeting at the CHC between the member and a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, 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.

HIV Pre-test Counseling Visit — a face-to-face meeting at the CHC between the member and a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, 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.

Home Visit — a face-to-face meeting between a member and a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, 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, certified nurse practitioner, clinical nurse specialist, 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, certified nurse practitioner, clinical nurse specialist, or registered nurse for medical examination, diagnosis, or treatment.

Individual Mental Health Visit —a face-to-face meeting at the CHC between a patient and either a psychiatrist or an advanced practice registered nurse (APRN) with a graduate degree and advanced training in psychiatric care (a psychiatric clinical nurse specialist or a psychiatric mental health nurse practitioner) within the community health center setting, for purposes of examination, diagnosis, or treatment.

Individual Therapy — psychotherapeutic services provided to an individual.

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.

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, physician assistant, or certified nurse practitioner 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 the MassHealth agency 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 licensed or certified in accordance with 130 CMR 426.404: *Provider Eligibility*. 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)

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

(A) Notification of Participation. Except for drugs that cost $100,000 or more per utilizer per year (gross cost per utilizer per year) that are designated as excluded from coverage for MassHealth members through the 340B Drug Pricing Program, a CHC that is a 340B-covered entity may provide drugs to MassHealth members through the 340B Drug Pricing Program provided that it notifies the MassHealth agency in writing that the 340B-covered entity is registered and approved by the federal Office of Pharmacy Affairs (OPA). Any high cost drug designated for exclusion from coverage for MassHealth members through the 340B Drug Pricing Program will be communicated by provider bulletin or other written issuance from the MassHealth agency, and be consistent with all requirements of M.G.L. c. 118E, §13L, and shall include an opportunity for eligible providers to provide input regarding the designation. The MassHealth agency may designate up to 25 drugs for exclusion from coverage for MassHealth members through the 340B Drug Pricing Program. Any exclusion from coverage for MassHealth members through the 340B Drug Pricing Program does not apply to claims paid using the adjudicated payment amount per discharge (APAD) or adjudicated payment per episode of care (APEC) methodology, other than for drugs listed on the Acute Hospital Carve-Out Drugs List section of the MassHealth Drug List.

(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: *Pharmacy Services*, and are subject to approval by the MassHealth agency.

(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, and is a MassHealth pharmacy provider, and that services are furnished in accordance with 130 CMR 406.000: *Pharmacy Services* and all other applicable MassHealth requirements including, but not limited to, those set forth in 130 CMR 450.000: *Administrative and Billing Regulations*.

(C) Termination or Changes in 340B Drug Pricing Program Participation. A CHC must provide the MassHealth agency 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 101 CMR 331.00: *Prescribed Drugs*.

405.467: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary community health care for EPSDT-eligible members in accordance with 130 CMR 450.140: *Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services: Introduction*, without regard to service limitations described in 130 CMR 405.000, and with prior authorization.

405.468: Drugs Administered in the CHC (Provider-administered Drugs)

(A) Drugs and biologicals dispensed in the CHC are payable, subject to the exclusions and service limitations at 130 CMR 405.417, 405.418, and 130 CMR 406.413(B): *Drug Exclusions* and (C): *Service Limitations*.

(B) The MassHealth agency does not pay separately for drugs that are considered routine and integral to the delivery of a service in the course of diagnosis or treatment. Such drugs are commonly provided without charge or are included in the CHC's fee for the service.

(C) The MassHealth agency does not pay separately for any oral drugs dispensed in the office for which the CHC has not requested and received prior authorization from the MassHealth agency, with the exception of oral vaccines and oral radiopharmaceuticals, which do not require prior authorization.

(D) Claims for drugs and biologicals that are listed in Subchapter 6 of the *Community Health Center Manual* must include the name of the drug or biological, strength, dosage, and number of Healthcare Common Procedure Coding System (HCPCS) units dispensed, National Drug Code (NDC), NDC units, and NDC unit of measurement. In addition, for drugs and/or biologicals that are listed as requiring individual consideration in Subchapter 6 of the *Community Health Center Manual*, a copy of the invoice showing the actual acquisition cost must be attached to the claim. Claims without this information are denied.

(E) The MassHealth agency pays only for prescription drugs that are approved by the U.S. Food and Drug Administration and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8. Payment is calculated in accordance with 101 CMR 331.00: *Prescribed Drugs.*

(F) The MassHealth agency does not pay for a biological if the Massachusetts Department of Public Health distributes the biological free of charge.

(G) Payment for drugs may be claimed in addition to an office visit.

(130 CMR 405.469 through 405.470 Reserved)

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 the MassHealth agency in writing of each service listed in 130 CMR 405.471(A) through (E) that the CHC will provide on site and must enroll with MassHealth as that provider type. All services provided on site must be furnished by practitioners qualified to provide the service that are employees or contactors of the CHC, and associated payment claimed by the CHC, in compliance with the applicable MassHealth regulations and Subchapter 6 for each service, including applicable fee schedules. All services listed below that are provided by referral must be based on written agreements between the CHC and each referral provider to ensure continuity of care, exchange of relevant health information such as test results and records, and avoidance of service duplication. Each referral provider must be a participating provider in MassHealth, and payment for the services provided by the referral provider must be claimed by the referral provider in compliance with the applicable MassHealth regulations for such service. All referrals must include follow up to ensure that the referral process is successfully completed. Services the CHC may elect to provide include:

(A) adult day health services;

(B) adult foster care;

(C) day habilitation;

(D) psychiatric day treatment; and

(E) home health services.

405.472: Tobacco-cessation Services

(A) Introduction. MassHealth members are eligible to receive tobacco cessation counseling services described in 130 CMR 405.472(B) and pharmacotherapy treatment, including nicotine replacement therapy (NRT), in accordance with 130 CMR 406.000*: Pharmacy Services*.

(B) Tobacco-cessation Counseling Services.

(1) MassHealth covers a total of 16 group and individual counseling sessions per member per 12-month cycle, without prior authorization. These sessions may be any combination of group and individual counseling. All individual counseling sessions must be at least 30 minutes, except for intake sessions, which must be at least 45 minutes. Intake sessions are limited to two per member per 12-month cycle, without prior authorization.

(a) Individual counseling consists of face-to-face tobacco-cessation counseling services provided to an individual member by a MassHealth-qualified provider of tobacco-cessation services as set forth in 130 CMR 405.472(B) and (C).

(b) Group tobacco treatment counseling consists of a scheduled professional counseling session with a minimum of three and a maximum of 12 members, and has a duration of at least 60 to 90 minutes.