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#### 409.401: Introduction

130 CMR 409.000 describes the requirements for the purchase, rental, and repair of durable medical equipment, and for the purchase of medical supplies under MassHealth. All durable medical equipment and supplies (DME) must be non-experimental, non-investigational, of proven quality and dependability, and must conform to all applicable federal and state product standards. All DME providers participating in MassHealth must comply with MassHealth regulations at 130 CMR 409.000 and 130 CMR 450.000: *Administrative and Billing Regulations*. The MassHealth agency may deny enrollment to an applicant or terminate participation of a MassHealth DME provider if the applicant or DME provider does not meet one or more of the requirements in 130 CMR 409.000.

#### 409.402: Definitions

The following terms used in 130 CMR 409.000 have the meanings given in 130 CMR 409.402 unless the context clearly requires a different meaning. Payment for services defined in 130 CMR 409.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 409.000, 101 CMR 322.00: *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*, and in 130 CMR 450.000: *Administrative and Billing Regulations*.

Absorbent Products – diapers or brief-like garments, underpads, liners, and shields used to contain and/or manage symptoms of incontinence. Absorbent products may be disposable, reusable, or washable.

Accessories – products that are used primarily and customarily to modify or enhance the usefulness or functional capability of an item of durable medical equipment and that are generally not useful in the absence of the item of durable medical equipment.

Accrediting Body – an organization acceptable to the Centers for Medicare & Medicaid Services (CMS) that accredits DME providers.

Agent – the person who has been delegated by the applicant or DME provider with the authority to obligate or act on behalf of a DME provider or applicant.

Ambulatory Equipment – DME that provides stability and security for members with impaired ambulation.

Applicant – an organization or individual who completes and submits an application to become a provider for MassHealth, but has not yet been determined by the MassHealth agency to be eligible to become a provider.

Assistive Technology Professional (ATP) – an individual with experience with assistive/rehabilitation technology who analyzes the equipment needs of persons with disabilities, assists in the selection of DME, and trains the person with the disability on how to use the specific equipment. This equipment may include manual and power wheelchairs, seating and alternative positioning, ambulation assistance, environmental control, alternate computer access, augmentative and alternative communication devices, and products of daily living.

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Augmentative and Alternative Communication Devices (AAC) – DME that are speech and communication aids that meet the functional speaking needs of members for whom such devices are medically necessary, with the exception of devices covered pursuant to 130 CMR 409.428(E).

Centers for Medicare & Medicaid Services (CMS) – a federal agency responsible for administering the Medicaid and Medicare programs created under the authority of Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), and Title XVIII of the Social Security Act (42 U.S.C. 1395-1395pp).

Clinical Nurse Specialist – a nurse who is in good standing with, and meets the requirements of, the Massachusetts Board of Registration of Nursing for Clinical Nurse Specialists, and all applicable federal and state requirements.

Compression Devices – products that are used for the treatment of lymphedema or chronic venous insufficiency with the goal of preventing the onset or worsening of venous stasis ulcers.

Consignment Closet – an arrangement in which a DME provider maintains inventory at an ordering practitioners’ location which is not the DME provider’s service facility, for delivery to members on behalf of the DME Provider.

Criminal Offender Record Information (CORI) – information regulated by the Criminal History Systems Board (CHSB) and defined under 803 CMR 2.03: *Definitions* to include records and data in any communicable form compiled by a criminal justice agency that concern an identifiable individual and relate to the nature or disposition of a criminal charge, an arrest, a pre-trial proceeding, other judicial proceedings, sentencing, incarceration, rehabilitation, or release.

Customized Equipment – durable medical equipment that

- (1) is uniquely constructed, adapted, or modified solely for the full time use of the member for whom the item is purchased;
- (2) is made to order or adapted to meet the specific needs of the member; and
- (3) is uniquely constructed, adapted, or modified to permanently preclude the use of such equipment by another individual.

Date of Service – the date the DME is delivered to or picked up by the member, with the exception of delivery of DME to a member in a hospital, nursing facility, or ICF/IID pursuant to 130 CMR 409.415(A)(1)(b), (C), (C)(1)(c) and 130 CMR 409.419(C) or, with prior authorization, services provided in excess of the otherwise applicable service limit pursuant to 130 CMR 409.418(F).

Department of Public Health – an agency of the Commonwealth of Massachusetts, established under M.G.L. c. 17, §1.

DME – as used in 130 CMR 409.000, DME means the durable medical equipment and medical supplies covered by 130 CMR 409.000.

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DME and Oxygen Payment and Coverage Guideline Tool – MassHealth web-based application that contains DME and oxygen service descriptions for all covered products and services, applicable modifiers, place-of service codes, prior authorization requirements, individual consideration requirements, service limits, markup information, and links to other applicable information, such as EOHHS and the Center for Health Information and Analysis (CHIA) websites. Subchapter 6 of the *Durable Medical Equipment Manual* directs providers to the MassHealth website for the DME and Oxygen Payment and Coverage Guideline Tool.

DME Provider – an organization or individual that has enrolled with MassHealth and has signed a provider contract with the MassHealth agency who meets all applicable requirements of 130 CMR 409.404 and 130 CMR 450.000: *Administrative and Billing Regulations*. DME providers may include providers also enrolled as MassHealth participating oxygen and respiratory therapy equipment and supplies (OXY) providers, orthotic services providers, or prosthetic services providers who meet all program-specific requirements; and MassHealth pharmacy providers eligible to enroll with a DME specialty under 130 CMR 409.404(C), who also meet all applicable requirements of 130 CMR 409.000.

Durable Medical Equipment (DME) – equipment that

- (1) is used primarily and customarily to serve a medical purpose;
- (2) is generally not useful in the absence of disability, illness or injury;
- (3) can withstand repeated use over an extended period; and
- (4) is appropriate for use in any setting in which normal life activities take place, other than a hospital, nursing facility, ICF/IID, or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board, except as allowed pursuant to 130 CMR 409.415 and 409.419(C).

Durable Medical Equipment Manual – provides DME regulations and other guidance issued by the MassHealth agency or its designee.

Enteral Nutrition – nutrition requirements that are provided via the gastrointestinal cavity by mouth (orally) or through a tube or stoma that delivers the nutrients distal to the oral cavity.

EOHHS – the Executive Office of Health and Human Services established under M.G.L. c. 6A.

Federal DME Face-to-face Requirements – CMS requirements promulgated in 42 CFR 440.70 which include the following requirements for payment for specific items of DME:

- (1) An in-person, face-to-face examination ~~with~~with a Medical Doctor (MD), Doctor of Osteopathic Medicine (DO), or non-physician practitioner: physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS);
- (2) Documentation from the practitioner or non-physician practitioner performing the face-to-face examination that the individual was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered; and
- (3) Occurrence of the face-to-face examination during the six months prior to the start of services.

Food and Drug Administration (FDA) – an agency of the United States Department of Health and Human Services that is responsible for the safety regulation of most types of foods, drugs, medical devices, and certain other products.

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Healthcare Common Procedure Coding System (HCPCS) – for purposes of 130 CMR 409.000, HCPCS refers to the Level II HCPCS codes which are maintained by CMS, and used by providers to bill for certain medical services, devices, and supplies, including all DME services.

Home – unless otherwise specified for purposes of rental and purchase of DME, a member’s home may be a dwelling owned or rented by the member, a relative’s or other person’s home in which the member resides, a rest home, assisted living, or another type of group residence or community setting in which normal life activities take place. A home does not include an institutional setting including but not limited to a hospital, nursing facility or Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board, except for items that are allowable pursuant to 130 CMR 409.415.

Home Infusion Therapy (HIT) Services – the administration of medications to a member in a home setting using delivery devices through intravenous, subcutaneous, or epidural routes. Drug therapies commonly administered include antibiotics, chemotherapy, pain management, parenteral nutrition, and immune globulin.

Hospital – a facility that is licensed or operated as a hospital by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health, or an out-of-state hospital facility enrolled as a provider in the MassHealth Acute Hospital or Chronic Disease and Rehabilitation Inpatient Hospital programs that provide diagnosis and treatment on an inpatient or outpatient basis for patients who have any of a variety of medical conditions.

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) – a facility, or distinct part of a facility, that provides intermediate care facility services as defined under 42 CFR § 440.150, and that meets federal conditions of participation, and is licensed by the state primarily for the diagnosis, treatment, or rehabilitation for individuals with intellectual disabilities; and provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration for health or rehabilitative services to help individuals function at their greatest ability.

Marketing – any communication from a DME provider, or its agent, to a member, or his or her family or caregivers, that can reasonably be interpreted as intended to influence the member’s choice of DME provider, whether by inducing that member

- (1) to retain that DME provider to provide DME services to the member;
- (2) not to retain DME services from another DME provider; or
- (3) to cease receiving DME services from another DME provider.

MassHealth – the medical assistance and benefit programs administered by EOHHS pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), M.G.L. c.118E, and other applicable laws and waivers to provider and pay for medical services to eligible members.

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Medical Supplies – consumable or disposable supplies or devices for home use necessary for the treatment of a specific illness, injury, disease, or disability, including, but not limited to test strips, syringes, ostomy products, and surgical items that are

- (1) required to address an individual’s medical disability, illness, or injury;
- (2) generally not useful in the absence of illness or injury;
- (3) consumable or disposable;
- (4) not able to withstand repeated use by more than one individual; and
- (5) appropriate for use in any setting in which normal life activities take place, other than a hospital, nursing facility, ICF/IID, or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board.

Medicare Competitive Bid Provider – Medicare-qualified provider chosen to provide Medicare-designated durable medical equipment and supplies in specified geographic areas for Medicare-specified time periods to MassHealth members with both Medicare and Medicaid coverage pursuant to 42 U.S.C. §1395w-3.

Member – a person determined by the MassHealth agency to be eligible for MassHealth.

Mobility System – a manual or power wheelchair or other wheeled device, such as a scooter, including a base, a seating system, its components, accessories, and modifications.

Non-physician Practitioner – a nurse practitioner or clinical nurse specialist working in collaboration with a physician or a physician assistant working under the supervision of a physician, who orders DME and writes the prescription for DME in accordance with 130 CMR 409.416.

Nurse Practitioner – a registered nurse who has successfully completed a formal education program for nurse practitioners as required by the Massachusetts Board of Registration of Nursing (the Board), who is in good standing with the Board, and who is responsible for oversight of the member’s health care. A nurse practitioner who prescribes medication must be certified by the federal Drug Enforcement Agency (DEA).

Nursing Facility (NF) – an institution (or a distinct part of an institution) which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, rehabilitation services for the rehabilitation of injured people, people with disabilities, or sick persons, or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services that meet the requirements of the Social Security Act §§1919(a), (b), (c) and (d) and is licensed under and certified by the Massachusetts Department of Public Health.

Nutritional Supplements – commercially prepared products primarily used to treat a diagnosed deficiency in the member’s diet or nutrition.

Office of Inspector General (OIG) – a federal agency established by law as an independent and objective oversight unit to carry out the mission of preventing fraud and abuse and promoting economy, efficiency, and effectiveness of HHS programs and operations, as defined by 5 U.S.C. App. 1.

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Ordering Practitioner – a physician or a non-physician practitioner who meets the requirements in 130 CMR 409.402, who orders DME and writes the prescription for DME in accordance with 130 CMR 409.416. For the purposes of 130 CMR 409.000, podiatrists are not ordering practitioners.

Ostomy Supplies – products used to contain diverted urine or fecal contents outside the body for patients who have a surgically created opening (stoma).

Parenteral Nutrition – nutrient requirements provided by means of a subcutaneous or intravenous route.

Personal Emergency Response System (PERS) – an electronic device connected to a person’s land-line telephone. In an emergency, it can be activated either by pushing a small button on a pendant or bracelet, pressing the help button on the console unit, or by an adaptive switch set-up. When the device is activated, a person from the 24-hours-per-day, seven-days-per week central monitoring station answers the call, speaks to the member *via* the console unit, assesses the need for help, and takes appropriate action.

Physician – a medical doctor or doctor of osteopathic medicine who is licensed by the Massachusetts Board of Registration in Medicine or by the appropriate board of registration in the state in which the physician practices.

Physician Assistant – a mid-level medical practitioner who works under the supervision of a licensed physician (MD) or osteopathic physician (DO) and who has graduated from an accredited physician assistant program and is certified by and in good standing with the Massachusetts Board of Physician Assistant Registration.

Prior Authorization (PA) Request – a request submitted by the DME provider, speech and language pathologist, or other entity as specified by MassHealth to the MassHealth agency to determine medical necessity in accordance with 130 CMR 409.417, 409.418, 409.428, 130 CMR 450.204: *Medical Necessity*, and 130 CMR 450.303: *Prior Authorization*.

Recall – action taken by the manufacturer of any item covered by 130 CMR 409.000 to retrieve, replace, or repair dangerous or defective DME, whether or not such action is taken at the direction of the Food and Drug Administration (FDA).

RESNA – the Rehabilitation Engineering and Assistive Technology Society of North America, or its successor.

Seating System – a seated positioning system, including its components, accessories, and modifications, which may be attached to a base wheelchair and is designed to meet the individualized medical needs of a member.

Service Facility – a DME business or branch of a DME business where MassHealth members can obtain services, equipment, and supplies, including, but not limited to, repairs, replacements, accessories, or returns.

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Serviceable Backup Mobility System – a manual wheelchair approved by the MassHealth agency as a backup to a power wheelchair as identified in 130 CMR 409.413(D) or a MassHealth member’s serviceable retired power wheelchair, that can be safely used by the MassHealth member when a manual backup or suitable loaner chair cannot be provided to meet the member’s medical needs pursuant to 130 CMR 409.420(G).

Subcontractor – an individual, agency, or organization

- (1) to which a MassHealth provider has contracted or delegated some of its management functions or responsibilities of providing medical care or services to members; or
- (2) with which a fiscal agent has entered into a contract, agreement, purchase order, or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the MassHealth agreement.

Support Surfaces – beds, mattresses, or overlays used to reduce or relieve pressure, prevent the worsening of pressure ulcers, or promote wound healing.

#### 409.403: Eligible Members

(A) MassHealth Members. MassHealth covers DME provided to eligible MassHealth members, subject to the restrictions and limitations described in 130 CMR 409.000 and 450.000: Administrative and Billing Regulations. ~~MassHealth regulations, and MassHealth regulations at 130 CMR 450.105: Coverage Types~~ specifically states, for each coverage type, which services are covered, and which members are eligible to receive those services.

(B) 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: *Emergency Aid to the Elderly, Disabled and Children Program*.

(C) Verification of Member Eligibility. For information about verifying member eligibility and coverage type, see 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

#### 409.404: Provider Eligibility

(A) Provider Participation Requirements. Payment for services described in 130 CMR 409.000 is made ~~only~~ to DME providers who ~~are participating in MassHealth, and to oxygen and respiratory therapy providers, or pharmacy providers who, as of the date of service,~~ are participating in MassHealth; to providers also enrolled as MassHealth-participating OXY providers, orthotic services providers, or prosthetic services providers and who meet all program-specific requirements; and to MassHealth-enrolled pharmacy providers who ~~and~~ have been assigned a DME specialty in accordance with 130 CMR 409.404(C) as of the date of service. Applicants must meet the requirements in 130 CMR 450.000: *Administrative and Billing Regulations* as well as the requirements in 130 CMR 409.000. Participating DME providers must continue to meet provider eligibility participation requirements throughout the period of their provider contract with the MassHealth agency.



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(B) General Qualifications. To qualify as a MassHealth DME provider, all applicants and providers must enter into a provider contract or agreement with MassHealth, and:

- (1) have a service facility that
  - (a) is open a minimum of 30 hours per week;
  - (b) is staffed with an employee during posted business hours;
  - (c) is available to members during regular, posted business hours;
  - (d) has available inventory for all products for which the DME provider has been accredited by an Accrediting Body, and for which the DME provider is enrolled in MassHealth, with the exception of items provided by subcontractors;
  - (e) is accessible to all members, including members with disabilities;
  - (f) has clear access and space for individualized ordering, returns, repair, and storing of business records;
  - (g) has a sign visible from outside the facility identifying the business name and hours that the service facility is open. If the DME provider's place of business is located within a building complex, the sign must be visible at the main entrance of the building where the service facility is located;
  - (h) has a primary business telephone number listed in the name of the business with a local toll-free telephone number that is answered by customer service staff during business hours, and that has TTY transmission and reception capability. During business hours, this number cannot be a pager, answering service, or voice message system; and
  - (i) during off hours, must maintain a voice message system and/or answering service;
- (2) obtain separate approval from the MassHealth agency and a separate provider number for each service facility operated by the DME provider;
- (3) ~~except for specialty providers described in 130 CMR 409.404(C), primarily~~ engage in the business of providing DME, or DME repair services, to the public;
- (4) be accredited by an Accrediting Body to participate or enroll in the Medicare program as a DME provider for the same business and service facility for which the applicant is applying to become a MassHealth provider, unless the provider supplies only items not covered by Medicare;
- (5) meet all applicable federal, state, and local requirements, certifications, and registrations;
- (6) conduct applicable Office of Inspector General (OIG) verifications on all staff;
- (7) at the time of application and recredentialing, or any other time as requested by the MassHealth agency, provide all required documentation specified in 130 CMR 450.000: *Administrative and Billing Regulations*, and updated documentation in accordance with 130 CMR 450.223(B) and 130 CMR 450.215: *Provider Eligibility: Notification of Potential Changes in Eligibility*, including:
  - (a) a list of contracted manufacturers used for purchased products
  - (b) a copy of all current liability insurance policies;
  - (c) a copy of the property lease agreement pertinent to the service facility, or a copy of the most recent property tax bill if applicant owns the business site;
  - (d) for mobility providers only, a copy of current RESNA ATP certificate for each certified staff member.
    1. DME providers who furnish mobility systems corresponding to one of the HCPCS codes for which CMS requires a certified ATP must employ at least one certified ATP at each service facility.

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2. The ATP at each service facility must possess knowledge of the standards of acceptable practice in the provision of DME including ordering, assembling, adjusting, and delivering DME, and providing ongoing support and services to meet a person's rehabilitation equipment needs;

- (e) a copy of all current signed employee professional licenses, as applicable;
  - (f) a copy of current accreditation letters;
  - (g) a copy of the purchase and sale agreement if the applicant or DME provider has recently been purchased by another entity or has purchased the company for which they are applying to become a MassHealth DME provider;
  - (h) a copy of subcontracts, if applicable, as described in 130 CMR 409.412. For PERS providers, the subcontract must include the central monitoring station contract, if applicable;
  - (i) a copy of the applicant's emergency preparedness plan as approved by the accrediting body;
  - (j) a copy of written policies and procedures, including the customer service protocol, customer complaint tracking and resolution protocol, the protocol on transfer and discharge of members, staff training; and
  - (k) for PERS providers only, a copy of documentation demonstrating compliance with UL Standards 1637 in accordance with 130 CMR 409.429(C);
  - (l) Controlled Substances Registrations through the Commonwealth of Massachusetts Department of Public Health, Division of Food and Drug (if provider provides oxygen);
  - (m) a Sterilization/Sanitation of Bedding, Upholstered Furniture, and Filling Materials License through the Department of Public Health, Division of Food and Drug (if applicable);
- (8) for a provider of home infusion services, be a licensed pharmacy in Massachusetts or in the state where the provider is located, and be accredited by an Accrediting Body, and be assigned a DME specialty by the MassHealth agency. *See* 130 CMR 409.404(C);
- (9) conduct pre-employment CORI checks on employees and subcontractors and keep CORIs on file at the DME provider's place of business;
- (10) not accept prescriptions for MassHealth DME from any ordering practitioner who has a financial interest in the DME provider;
- (11) cooperate with the MassHealth agency or its designee during the application and recredentialing process, including, but not limited to, site visits or periodic inspections to ensure compliance with 130 CMR 409.000 and applicable state and federal laws and regulations; and
- (12) comply with applicable CMS provider requirements, including supplier standards listed at 42 CFR 424.57(c) and any CMS or MassHealth quality standards.

(C) Providers Assigned DME Specialty. ~~An applicants or providers whose primary business is not DME enrolled as a MassHealth provider of pharmacy services under 130 CMR 406.000:~~ Pharmacy Services may qualify to provide DME services if the following conditions are met:

- (1) the applicant or provider ~~is enrolled as a MassHealth provider of oxygen and respiratory therapy equipment services under 130 CMR 427.000: Oxygen and Respiratory Therapy Equipment or pharmacy services under 130 CMR 406.000: Pharmacy Services;~~
- (2) ~~the applicant or provider~~ meets all other conditions under 130 CMR 409.404 and 405 to provide DME services; and

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(23) MassHealth has assigned a specialty of DME to the applicant's or provider's existing provider number for ~~oxygen and respiratory therapy equipment services or~~ pharmacy services; or

(34) the MassHealth agency has determined that the applicant proposes to provide repairs of DME and meets the MassHealth agency requirements for participation as a DME repair provider.

(D) In State. To qualify as an in-state DME provider, the applicant or provider must have a service facility located in Massachusetts that meets the criteria described in 130 CMR 409.404(B)(1).

(E) Out of State. An applicant or provider of DME with a service facility located outside of Massachusetts may qualify as a MassHealth DME provider only if the following condition is met:

- (1) all applicable requirements under 130 CMR 409.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, and 42 CFR 431.52 are met;
- (2) the out-of-state DME provider participates in the Medicaid program of the state in which the provider primarily conducts business;
- (3) the DME provider participates in the Medicare program, unless the DME provider provides only PERS or absorbent products;
- (4) the provider has a service facility that can readily replace and repair products when needed by the member; and
- (5) the MassHealth agency has determined that the out-of-state applicant proposes to provide durable medical equipment or supplies that meet a need identified by the MassHealth agency.

#### 409.405: Provider Responsibilities

In addition to meeting all other provider requirements set forth in 130 CMR 409.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, the DME provider must:

(A) accept, as payment in full, rates of payment established by EOHHS through regulations at 101 CMR 322.00 *Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment*, including as determined by the MassHealth agency through a preferred supplier contracting process or by other means;

(B) comply with all applicable Medicare billing and authorization requirements and make diligent efforts to identify and obtain payment from all other liable parties including Medicare, before billing MassHealth, in accordance with 130 CMR 450.316: *Third-party Liability: Requirements* through 130 CMR 450.318: *Third-party Liability: Payment Limitations on Medicare Crossover Claim Submissions* and, all subregulatory guidance. This includes appealing a denied claim, before filing a MassHealth claim, when the service is payable in whole or in part by Medicare or other liable parties or payers. If documentation requested by the MassHealth agency, or its designee, is not received within the timeframe specified by the MassHealth agency or its designee, or the documentation is incomplete or does not support coverage by MassHealth, the associated claims will be denied. Failing to seek payment from all other liable parties may result in an overpayment pursuant to 130 CMR 450.235(A)(4).