Commonwealth of Massachusetts
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MASSHEALTH
TRANSMITTAL LETTER FPA-39
October 2005

TO: Family Planning Agencies Participating in MassHealth

FROM: Beth Waldman, Medicaid Director

RE: *Family Planning Agency Manual* (Revised Regulations and Updates to Subchapter 6)

This letter transmits revised regulations for family planning agencies. The regulations have been updated to

- reflect current standards of care;
- provide coverage for HIV pre- and post-test counseling in family planning agencies;
- use American College of Gynecology Standards to determine frequency of covered Pap smears;
- increase the provider recordkeeping requirement from four to six years; and
- eliminate specific language about Norplant. Implantable contraceptives remain covered services.

This letter also transmits revisions to Subchapter 6 (Service Codes and Descriptions) of the *Family Planning Agency Manual*. The revisions include the addition of service codes for HIV pre- and post-test counseling and for hormone-containing vaginal rings, and the elimination of language specific to Norplant for the codes for implantable contraceptives. (The codes for implantable contraceptives remain in Subchapter 6; only the references to Norplant in the code description have been removed.)

These regulations are effective November 1, 2005.

If you have any questions about the information in this transmittal letter please contact MassHealth Customer Service at 1-800-841-2900, e-mail 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.)

Family Planning Agency Manual

Pages iv, 4-1 through 4-16, 6-1, and 6-2

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(The pages listed here are no longer in effect.)

Family Planning Agency Manual

Pages iv, 4-1 through 4-18 — transmitted by Transmittal Letter FPA-29

Pages 6-1 and 6-2 — transmitted by Transmittal Letter FPA-37

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421.401: Introduction

All providers of family planning agency services participating in MassHealth must comply with the MassHealth regulations at 130 CMR 421.000 and 130 CMR 450.000.

421.402: Definitions

The following terms used in 130 CMR 421.000 have the meanings given in 130 CMR 421.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 421.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 421.000 and in 130 CMR 450.000.

Annual Visit – a yearly visit during which comprehensive services, including medical, laboratory, and counseling services are provided.

HIV Pre- and Post-Test Counseling Visit – a face-to-face meeting between the member and a counselor for the purpose of providing counseling before and after HIV testing. Such counseling includes 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.

Initial Visit – a member’s first visit during which comprehensive services, including medical, laboratory, and counseling services are provided.

Institutionalized Individual – 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 – 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.

Minimal Visit – a brief visit during which a family planning agency provides counseling services only or brief medical and counseling services.

Routine Visit – a return visit, follow-up visit, or other visit that is neither an annual nor an initial visit.

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.

421.403: Eligible Members

(A) (1) MassHealth Members. MassHealth covers family planning agency services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in the 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 about verifying member eligibility and coverage types, see 130 CMR 450.107.

421.404: Provider Eligibility

Payment for the services described in 130 CMR 421.000 is made only to family planning agencies that are participating in MassHealth as of the date of service. The eligibility requirements for family planning agencies are as follows.

(A) In State.

(1) A family planning agency located in Massachusetts is eligible to participate in MassHealth only if it is certified by the MassHealth agency as a family planning agency, in accordance with the requirements specified in 130 CMR 421.404 through 421.427.

(2) The family planning agency must fulfill one of the following licensing requirements.

(a) Family planning services must be provided in a facility licensed as a clinic or hospital by the Massachusetts Department of Public Health.

(b) Family planning services must be provided under the supervision of a physician licensed by the Massachusetts Board of Registration in Medicine.

(3) A family planning agency may provide family planning services in one or more service delivery sites, which must be located in freestanding clinics, community health centers, hospital outpatient departments, or hospital-licensed health centers.

(B) Out of State. A family planning agency located outside of Massachusetts is eligible to participate in MassHealth only if it meets the licensing requirements in its state, participates in that state's Medicaid program (or equivalent), and meets the requirements specified in 130 CMR 421.404(3) through 421.427.

421.405: Staffing

(A) Personnel Policies.

(1) Current job descriptions must be available for all positions of the staff.

(2) Written personnel policies must be available to all personnel.

(3) An evaluation and review of the job performance of all personnel must be conducted annually.

(B) Personnel Qualifications and Responsibilities.

(1) Administrator. A family planning agency must employ a full-time administrator who is responsible for supervising family planning services and for managing the family planning agency. The administrator must have demonstrated experience in the area of health-care administration.

(2) Medical Director. A family planning agency must employ a medical director who is a physician licensed by the Massachusetts Board of Registration in Medicine and who has demonstrated familiarity with gynecological examination and contraceptive prescription. The medical director is responsible for coordinating medical-staff activities as well as the medical aspects of the family planning program. The medical director assumes responsibility for the implementation of family planning protocol (see 130 CMR 421.412(E)); the maintenance of clinic standards; and the credentials review, training, and supervision of all staff physicians, nurse practitioners, and other medical personnel.

(3) Physician. A physician who is licensed by the Massachusetts Board of Registration in Medicine and who has demonstrated familiarity with gynecological examination and contraceptive prescription may provide medical care and medical supervision in a family planning agency. A physician must be either on site or on call during all clinic sessions.

(4) Nurse Practitioner. A nurse practitioner who is licensed by the Massachusetts Board of Registration in Nursing may work in a family planning agency in collaboration with a physician. A nurse practitioner must comply with all conditions of licensure and certification, including all statutory and regulatory provisions governing nurse practitioner practice. On the basis of the nurse practitioner's education, experience, and clinical skills, the medical director must define and must reevaluate annually the nurse practitioner's responsibilities.

(5) Physician Assistant. A physician assistant who is a graduate of a program approved by the Massachusetts Board of Approval and Certification of Physician Assistant Programs may work in a family planning agency under the supervision of a physician. A physician assistant must comply with all statutory and regulatory provisions governing physician-assistant practice. On the basis of the physician assistant's education, experience, and clinical skills, the supervising physician must define and must reevaluate annually the physician assistant's responsibilities.

(6) Nurse. A nurse who is licensed by the Massachusetts Board of Registration in Nursing as a registered nurse or a licensed practical nurse may assist the physician, take medical histories, and conduct patient education and instruction about contraception in a family planning agency.

(7) Counselor or Outreach Worker. A counselor or outreach worker who has studied human anatomy and physiology, human reproduction, contraceptive methods, and counseling techniques may provide patient education, counseling, follow-up, and community education for a family planning agency.

(C) In-Service Training. Family planning agency personnel must participate in continuing education programs related to their activities, including orientation, on-the-job training, and regular in-service training.

(130 CMR 421.406 through 421.410 Reserved)

421.411: Certification

The MassHealth agency certifies only a comprehensive family planning agency, defined as a public or private agency that demonstrates the capability of providing family planning medical services, family planning counseling services, follow-up health care, outreach, and community education.

421.412: Medical and Laboratory Services

(A) For an initial or annual visit, a family planning agency must provide all of the following medical and laboratory services:
(1) a complete medical history (including family and interval);
(2) a physical examination:
(a) for a member who is female, this includes thyroid, breast, heart, abdominal, speculum, pelvic, and rectal examinations, and measurements of height, weight, and blood pressure;
(b) for a member who is male, this includes thyroid, heart, genital, abdominal, and rectal examinations, and measurements of height, weight, and blood pressure;
(3) a Pap smear (for a female member) as indicated by current nationally recommended protocols, such as American College of Obstetrics and Gynecology (ACOG), American Cancer Society (ACS), or the US Preventive Services Task Force (USPSTF);
(4) any laboratory test indicated by the member's history or examination (such a test may be provided directly or by referral);
(5) a medically approved method of contraception, if appropriate; and
(6) referrals for the screening, diagnosis, prevention, or treatment of general as well as reproductive medical conditions.

(B) For a routine visit, a family planning agency must provide medical and laboratory services necessary to monitor the member's contraceptive care or to follow-up on conditions requiring medical attention by agency personnel. These services must include, but are not limited to, the following:
(1) update of medical history;
(2) a physical examination that may include pelvic or genital examination;
(3) measurements of blood pressure and weight;
(4) any laboratory test indicated by the member's history or examination (such a test may be provided directly or by referral);
(5) identification of any symptoms, conditions, or side effects that may contraindicate the method of contraception used;
(6) assessment of the member's use of the method of contraception; and
(7) referrals for the screening, diagnosis, prevention, or treatment of general as well as reproductive medical conditions.

(C) For a minimal visit, a family planning agency must provide counseling services only or brief medical and counseling services. The purpose of a minimal service visit is to reinforce contraceptive instructions, to monitor the member’s use of a contraceptive method, or to provide education and counseling.

(D) A family planning agency must make available all methods of contraception listed in Subchapter 6 of the *Family Planning Agency Manual*.

(E) Physical examinations must be performed by a physician, a nurse practitioner, or a physician assistant. A physician must examine all members with medical problems and members who request to be seen by a physician. A nurse practitioner or physician assistant may examine members during an initial, annual, or routine visit. A physician must be on site or on call during all hours of operation.

(F) The family planning agency must have written medical protocols that include a periodicity schedule for return visits, procedures for follow-up for each method of contraception, procedures for care of high-risk patients, and emergency drug protocols.

421.413: Counseling

A family planning agency must provide counseling to assist members in achieving their family planning goals. Such counseling may include discussing general health, human anatomy, physiology, reproduction, and all available methods of contraception. Specific information about the safety of a method (potential side effects or complications), its effectiveness, its acceptability to member and partner, and its correct usage must be given. Surgical procedures must be discussed if the member prefers a permanent method of contraception. Follow-up counseling may include reinforcement of contraceptive instructions and reproductive information, discussion of member concerns or problems, and additional education.

421.414: Follow-Up and Referral

(A) Follow-Up. The family planning agency must have a system of contacting members who are patients of that family planning agency to remind them of their annual visits.

(B) Referral.
(1) A family planning agency must have arrangements with medical, social-service, and other community-service agencies to which appropriate referrals may be made for member problems identified during a family planning visit. The family planning agency must make referrals for necessary services if those services are not available on site. These services include, but are not limited to, the following:
(a) treatment of medical problems beyond the scope of the family planning agency;
(b) follow-up on positive results of tests for sexually transmitted disease or on other laboratory tests;
(c) pregnancy-related services;
(d) genetic counseling;
(e) sterilization services or information; and
(f) social case work beyond the scope of the family planning agency.
(2) All referrals must include follow-up to ensure that the referral process is completed successfully. If the referral was for an abnormal laboratory test result or a reproductive health problem, follow-up must include arrangements for receiving written results of tests or a report of initiated treatment.

421.415: Community Education

(A) A family planning agency must provide community education. The objectives of a community education program include, but are not limited to, the following:

(1) promoting community awareness and support of family planning services;

(2) providing information about family planning or reproduction to interested groups or individuals;

(3) integrating family planning education into educational institutions and community organizations; and

(4) being a resource for other professionals in family planning education.

(B) A community education program must attempt to address the objectives in 130 CMR 421.415(A) through methods that are appropriate to the needs of the community. Such methods must include at least two of the following:

(1) educational programs for adolescents, parents, professionals, and other targeted groups;

(2) consultations with community organizations, schools, or church groups;

(3) workshops or conferences;

(4) health fairs;

(5) speaking engagements;

(6) media activities (for example, television or radio talk shows and newspaper articles);

(7) participation in curriculum development and implementation; or

(8) development of educational materials.

421.416: Outreach

(A) A family planning agency must perform outreach activities. The objectives of an outreach program include, but are not limited to, the following:

(1) to make known to an entire community the availability of family planning services;

(2) to encourage use of the agency's services by certain populations, such as adolescents and persons eligible for MassHealth, that are not currently receiving services adequate to meet their needs; and

(3) to build linkages and referrals with local agencies and professionals.

(B) An outreach program must attempt to address the objectives in 130 CMR 421.416(A) through methods that are appropriate to the needs of the community. Any of the methods for providing community education that are listed in 130 CMR 421.415(B) may also be used for outreach. In addition, outreach methods must include one or more of the following:

(1) publications for distribution;

(2) advertisements;

(3) public-service announcements and media spots;

(4) information disseminated to groups and individuals in the target populations and, to the extent possible, in the native language and in the locality of the populations;

(5) contact and information exchange with local transitional assistance offices; and

(6) establishment of referral agreements with local agencies and professionals.

421.417: Noncovered Services

The MassHealth agency does not pay for the treatment of male or female infertility, including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment.

(130 CMR 421.418 through 421.420 Reserved)

421.421: Coordination of Services

When a family planning agency is located in a community health center, a hospital, or another primary-care setting, the agency must demonstrate that family planning services are coordinated with and integrated into other services delivered on site. Such coordination includes at a minimum:

(A) either one central medical record for each member in which all medical and health-care services are recorded, or a mechanism for transferring relevant information to medical records to ensure continuity of care;

(B) avoidance of duplication of medical examinations and laboratory tests; and

(C) in-house referrals, as appropriate.

421.422: Emergency Backup

A family planning agency must have provisions for 24-hour emergency backup. Each member must be given the emergency telephone number in writing at the time of initiation of services. The telephone number must also be displayed prominently in the family planning agency.

421.423: Recordkeeping Requirements

(A) Payment for any service listed in 130 CMR 421.000 is conditioned upon its full and complete documentation in the member's medical record. A family planning agency must maintain a record of all medical and contraceptive services provided to a member for at least six years following the date of service. Every member visit or telephone call with the staff must be recorded. The documentation must include the reason for each visit or telephone call and any action taken.

(B) The medical record must contain, but is not limited to, 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 person performing the service or making the contact;
(4) the type of visit (for example, annual or routine);
(5) medical history and history update;
(6) pertinent findings on examination;
(7) laboratory tests and results;
(8) abnormal findings and follow-up treatment;
(9) drugs administered or prescribed, including strength, dosage, route, regimen, and number of refills;
(10) drugs dispensed, including strength, dosage, route, regimen, and number of units;
(11) the contraceptive method used and any special instructions;
(12) a summary of counseling; and
(13) plans for follow-up.

(C) Basic information collected during previous visits with the member (for example, identifying data or medical history) does not need to be repeated in the medical record for subsequent visits as long as the entire medical record reflects continuity of care.

421.424: Quality Assurance

(A) Medical.

(1) The medical director or his or her designee must perform an on-site review of all physicians, nurse practitioners, and physician assistants within the first three months of their employment and thereafter annually for physicians and semiannually for nurse practitioners and physician assistants. Written reports of these reviews must be included in the personnel file. The on-site review must include observation and assessment of the clinical skills of the practitioner in caring for a variety of patients.

(2) The medical director or his or her designee must review at least four times a year a sample of the agency's records for adequacy of documentation and appropriateness of treatment and follow-up.

(B) General. A family planning agency must have ongoing evaluation processes and appropriate plans of action for all program activities (including counseling and outreach services), clinic management, and availability of services.

(130 CMR 421.425 Reserved)

421.426: Consumer Participation

A family planning agency must be responsive to its consumers' needs and desires. A family planning agency must have at least one consumer on its board or a consumer advisory group. Consumer representatives may not be employed by the agency while they are members of the board or group. Matters subject to review by the board or group must include, but are not limited to, policy development, service delivery, and program evaluation.

421.427: Assurance of Member Rights

(A) Services must be made available to all members who request services, without regard to race, color, national origin, religion, creed, age, sex, parity, marital status, or handicap.

(B) A member's use of family planning services must be completely voluntary. No provider may coerce members in any way to receive services or to employ any particular method of family planning. Neither the MassHealth agency nor any provider, nor any agent or employee of a provider, may mislead any member into believing that a decision to accept or not to accept family planning services will adversely affect his or her entitlement to benefits or services.

(C) The design of the agency's facilities must ensure privacy, confidentiality, and regard for the dignity of the member during personal interviews, consultations, medical examinations, and treatment. All information disclosed to agency personnel by the member or found as a result of the member's examination, care, and treatment must be held in strict confidentiality.

(130 CMR 421.428 through 421.430 Reserved)

421.431: Maximum Allowable Fees

The Massachusetts Division of Health Care Finance and Policy determines the maximum allowable fees for family planning agency services. Payment is always subject to the conditions, exclusions, and limitations set forth in 130 CMR 421.000. The payment for a service is the lower of the following:

(A) the amount specified in the applicable fee schedule of the Division of Health Care Finance and Policy; or

(B) the agency's usual and customary fee (if the agency uses a sliding fee scale, this is the highest level of the scale).

421.432: Payment: Visits

(A) The payment for a family planning visit includes payment for the administrative operation of the family planning agency and for all aspects of service delivery, excluding laboratory tests, supplies, and drugs. Other than payment for laboratory tests, supplies, and drugs, no additional fees will be paid by the MassHealth agency.

(B) For each member encounter, the MassHealth agency pays for only one of the following types of visits.

(1) Comprehensive Visit. The MassHealth agency pays for a comprehensive visit only when the encounter is an initial, annual, or extended visit. An initial or annual visit must include all of the medical, laboratory, and counseling services required in 130 CMR 421.412(A) and 421.413. The MassHealth agency pays for only one initial or annual visit per member per year. An encounter is considered to be an extended visit when it is not routine in nature because extensive medical attention is necessary. Such a visit must last approximately 30 minutes. For an extended visit, the need for such services and the time elapsed must be documented in the medical record by the physician. The MassHealth agency pays for HIV pre- and post-test counseling services in addition to a comprehensive visit.

(2) Routine Visit. The MassHealth agency pays for a routine visit when the encounter is a return, follow-up, or other visit that is neither comprehensive nor minimal. A routine visit must include all of the medical, laboratory, and counseling services required in 130 CMR 421.412(B) and 421.413. The MassHealth agency pays for HIV pre- and post-test counseling services in addition to a routine visit.

(3) Minimal Service Visit. The MassHealth agency pays for a minimal service visit when the encounter is a return visit consisting of counseling services only, or of a brief medical encounter and counseling services. The purpose of a minimal service visit is to reinforce contraceptive instructions, to monitor the member's use of a contraceptive method, or to provide education and counseling. A minimal service visit may not be billed in addition to HIV pre- and post-test counseling services.

(C) The MassHealth agency does not pay for a visit for the sole purpose of replenishing a member's supply of contraceptives. In this case, only the cost of the contraceptive supplies is payable.

(D) The family planning agency may bill for either a visit or a treatment/procedure, but may not bill for both a visit and a treatment/procedure for the same member on the same date when the visit and the treatment/procedure are performed in the same location. Examples of treatment/procedures are a vasectomy, a colposcopy, and a colposcopy with a biopsy.

(E) The family planning agency may be paid for a maximum of one HIV pre-test counseling visit and one HIV post-test counseling visit per member per test per day. The MassHealth agency pays for a maximum of four HIV pre-test counseling visits and four HIV post-test counseling visits per calendar year.

421.433: Payment: Laboratory Services

(A) Covered Services. The MassHealth agency pays for laboratory services listed in Subchapter 6 of the *Family Planning Agency Manual* that are performed either at the agency or at an outside laboratory as a result of specimen referral. For tests performed at an outside laboratory, the MassHealth agency pays according to the laboratory's charge to the agency or the laboratory fee schedule amount, whichever amount is less.

(B) Noncovered Services. The MassHealth agency does not pay separately for routine specimen collection and preparation for the purpose of clinical laboratory analysis (for example, venipunctures; urine, fecal, and sputum samples; Pap smears; cultures; and swabbing and scraping for removal of tissue). The MassHealth agency does not pay for laboratory tests associated with male or female infertility or such calculations as red blood cell indices, A/G ratio, creatinine clearance, and those ratios calculated as part of a profile.

(C) Profile or Panel Tests.
(1) A profile or panel test is defined as any group of tests, whether performed manually, automatedly, or semiautomatedly, that is ordered for a specified member on a specified day and has at least one of the following characteristics.
(a) The group of tests is designated as a profile or panel by the family planning agency performing the tests.
(b) The group of tests is performed by the agency at a usual and customary fee that is lower than the sum of that agency's usual and customary fees for the individual tests in that group.
(2) In no event may a family planning agency bill or be paid separately for each of the tests included in a profile test when a profile test has either been performed by that agency or requested by an authorized person.

(D) Individual Consideration. Some services listed in Subchapter 6 of the *Family Planning Agency Manual* are designated "I.C.," an abbreviation for individual consideration. This means that a specific fee could not be established. The payment for an I.C. service is determined by the MassHealth agency’s professional advisors based on the name of the test entered on the claim form.

421.434: Payment: Contraceptive Supplies and Drugs

(A) Contraceptive Supplies. The MassHealth agency pays for contraceptive supplies listed in Subchapter 6 of the *Family Planning Agency Manual*. If the family planning agency purchases supplies at a price lower than that allowed in the fee schedule, the agency must bill the MassHealth agency at that lower price.

(B) Drugs. The MassHealth agency pays for drugs at the actual acquisition cost. A copy of the current invoice showing the actual acquisition cost must be attached to the claim form. Claims for dispensing drugs must include the following information: the name of the drug; the strength; the dosage; and the number of units. Claims without this information will be denied. Payment for drugs is determined on an individual consideration (I.C.) basis by the MassHealth agency, based on the information entered on the claim form.

(130 CMR 421.435 through 421.437 Reserved)

421.438: Sterilization Services: Introduction

(A) Covered Services. The MassHealth agency pays for a sterilization service provided to a member who is male only if all of the following conditions are met.

(1) The member has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 421.439, and such consent is documented in the manner and form described in 130 CMR 421.440.

(2) The member is at least 18 years old at the time consent is obtained.

(3) The member is not a mentally incompetent or institutionalized individual.

(B) Assurance of Member Rights. No provider may use any form of coercion in the provision of sterilization services. No provider, or agent or employee of a provider, may mislead any member into believing that a decision to have or not to have a sterilization will adversely affect the member's entitlement to benefits or services for which the member would otherwise be eligible.

(C) Retroactive Eligibility. The MassHealth agency does not pay for a sterilization performed during the period of a member's retroactive eligibility unless all conditions for payment listed in 130 CMR 421.438(B) are met.

(D) Location in Which Sterilizations May Be Performed. Male sterilization must be performed by a licensed physician at the family planning agency's site.

421.439: Sterilization Services: Informed Consent

A member's consent for sterilization is considered informed and voluntary only if such consent was obtained in accordance with the requirements specified in 130 CMR 421.439(A) and (B).

(A) Informed Consent Requirements.

(1) The person who obtains consent (a physician, nurse, or counselor, for example) must orally provide all of the following information and advice to the member requesting sterilization:

(a) advice that the member is free to withhold or withdraw consent for the sterilization procedure at any time prior to that procedure without affecting the right to future care or treatment and without loss of any federal- or state-funded program benefits to which the member might be entitled;

(b) a description of available alternative methods of family planning and birth control;

(c) advice that the sterilization procedure is considered irreversible;

(d) a thorough explanation of the specific sterilization procedure to be performed;

(e) a full description of the discomforts and risks that may accompany or follow the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(f) a full description of the benefits or advantages that may be expected as a result of the sterilization; and

(g) advice that the sterilization will not be performed for at least 30 days from the date consent is given.

(2) The person who obtains consent must also:
(a) offer to answer any questions the member may have concerning the sterilization procedure;
(b) give the member a copy of the consent form;
(c) make suitable arrangements to ensure that the information and advice required by 130 CMR 421.439(A)(1) are effectively communicated to any member who is blind, deaf, or otherwise handicapped;
(d) provide an interpreter if the member does not understand the language used on the consent form or the language used by the person obtaining consent; and
(e) allow the member to have a witness of the member's choice present when consent is obtained.

(B) When Informed Consent Must Be Obtained.
(1) A member's consent for sterilization is considered informed and voluntary only if such consent was obtained at least 30 days, but not more than 180 days, before the date of the sterilization procedure.
(2) A member's consent for sterilization is not considered informed or voluntary if such consent was obtained or given while the member requesting sterilization was under the influence of alcohol or other substances that affect the individual's state of awareness.
(3) Shortly before the performance of the sterilization procedure, the physician performing the procedure must orally inform the member of all of the information and advice specified in 130 CMR 421.439(A)(1).

421.440: Sterilization Services: Consent Form Requirements

Informed consent for sterilization must be documented by the completion of the MassHealth agency's Consent for Sterilization form in accordance with the following requirements. (Instructions for obtaining the Consent for Sterilization forms are located in Subchapter 5 of the *Family Planning Agency Manual*.)

(A) Required Consent Form.
(1) One of the following Consent for Sterilization forms must be used:
(a) CS-18 – for members aged 18 through 20; or
(b) CS-21 – for members aged 21 and older.
(2) Under no circumstances will the MassHealth agency accept any other consent for sterilization form.

(B) Required Signatures. The member, the interpreter (if one was required), and the person who obtained the consent for sterilization must all sign and date the Consent for Sterilization form (CS-18 or CS-21) at the time of consent. After performing the sterilization procedure, the physician must sign and date the form.

(C) Required Submission and Distribution of the Consent Form. Providers must complete and distribute the Consent for Sterilization form (CS-18 or CS-21) as follows:

(1) the original to the member at the time of consent;

(2) a copy in the member's permanent medical record at the site where the sterilization is performed; and

(3) a copy attached to each claim made to the MassHealth agency for sterilization services.

REGULATORY AUTHORITY

130 CMR 421.000: M.G.L. c. 118E, §§ 7 and 12.

601 Definitions

(A) New Patient – a patient who has not received any professional services from the provider within the past three years.

(B) Established Patient – a patient who has received professional services from the provider within the past three years.

602 Service Codes and Descriptions: Visits

Service Code	Service Description
	New Patient
99201	Office or other outpatient visit for the evaluation and management of a new patient, which requires these three key components: - a problem-focused history; - a problem-focused examination; and - straightforward medical decision making (brief service)
99203	Office or other outpatient visit for the evaluation and management of a new patient, which requires these three key components: - a detailed history; - a detailed examination; and - medical decision making of low complexity
99205	Office or other outpatient visit for the evaluation and management of a new patient, which requires these three key components: - a comprehensive history; - a comprehensive examination; and - medical decision making of high complexity (comprehensive service)
	Established Patient
99211	Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician (minimal service)
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least two of these three key components: - an expanded problem-focused history; - an expanded problem-focused examination; - medical decision making of low complexity (limited service)
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least two of these three key components: - a comprehensive history; - a comprehensive examination; - medical decision making of high complexity (comprehensive service)

602 Service Codes and Descriptions: Visits (cont.)

Service
Code Service Description

Preventive Medicine, Individual Counseling

99402 Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 30 minutes (HIV pre- and post-test counseling only; two visits per day; maximum eight visits per year)

603 Service Codes and Descriptions: Contraceptive Supplies and Drugs

Service
Code Service Description

A4261 Cervical cap for contraceptive use (I.C.)
A4266 Diaphragm for contraceptive use (includes applicator and cream or jelly)
A4267 Contraceptive supply, condom, male, each
A4268 Contraceptive supply, condom, female, each
A4269 Contraceptive supply, spermicide (e.g., foam, gel), each (per package/tube)
J1055 Injection, medroxyprogesterone acetate for contraceptive use, 150 mg (Use for Depo-Provera.) (I.C.)
J1056 Injection, medroxyprogesterone acetate/estradiol cypionate, 5 mg/25 mg (Use for Lunelle monthly contraceptive.) (I.C.)
J3490-FP Unclassified drugs (Use for medications and injectibles related to family planning services, with the exception of (a) Rh_o(D) human immune globulin; and (b) contraceptive injectables such as Depo-Provera, items for which MassHealth will pay the provider's cost.) (I.C.)
J7303 Contraceptive supply, hormone-containing vaginal ring, each
J7304 Contraceptive supply, hormone-containing patch, each
S4989 Contraceptive intrauterine device (e.g., Progestacert IUD), including implants and supplies (I.C.)
S4993 Contraceptive pills for birth control

604 Service Codes and Descriptions: Medical and Surgery Procedures

Service
Code Service Description

11975 Insertion, implantable contraceptive capsules
11976 Removal, implantable contraceptive capsules (S.P.)
11977 Removal with reinsertion, implantable contraceptive capsules
19100 Biopsy of breast; percutaneous, needle core, not using imaging guidance (separate procedure)
49080 Peritoneocentesis, abdominal paracentesis, or peritoneal lavage (diagnostic or therapeutic); initial
55250 Vasectomy, unilateral or bilateral (separate procedure), including postoperative semen examination(s) (Consent for Sterilization form CS-18 or CS-21 required)
55450 Ligation (percutaneous) of vas deferens, unilateral or bilateral (separate procedure) (Consent for Sterilization form CS-18 or CS-21 required)
56420 Incision and drainage of Bartholin's gland abscess
56501 Destruction of lesion(s), vulva; simple (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery)
56605 Biopsy of vulva or perineum (separate procedure); one lesion
56606 each separate additional lesion (List separately in addition to code for primary procedure.)