



Medicaid Evidence Based Benefit Review Advisory Committee (EBBRAC) Bylaws

I. Introduction

The name of this Advisory Committee is the Medicaid Evidence Based Benefit Review Advisory Committee (EBBRAC). This Advisory Committee was established pursuant to Chapter 57, Part B, section 46-a of the Laws of 2015 as Social Services Law Section 365-d.

II. Purpose and Responsibilities of the EBBRAC

- a. Pursuant to Social Services Law section 365-d (1), this Advisory Committee is charged to provide advice and make recommendations regarding coverage of health technology or service for purposes of the Medicaid program. The Commissioner of the NYS Department of Health (Commissioner) shall consult with EBBRAC (the Committee) prior to any determination made regarding the coverage status of a particular item, health technology or service based on procedures established pursuant to Social Services Law section 365-d (5) under the Medicaid program.
- b. EBBRAC shall consider matters regarding “material changes” in the coverage status of a particular item, “health technology” or “service”, and matters relative to a new health technology assessment or a medical evidence review for which the NYS Department of Health (the Department) determines a sufficient body of evidence exists to warrant Committee deliberation. Under this law: a) “health technology” means medical devices and surgical procedures used in the prevention, diagnosis and treatment of disease and other medical conditions and b) “services” means any medical or behavioral health procedure.

III. Composition

- a. EBBRAC shall consist of, at a minimum, fourteen members, including the Chairperson, who is designated by the Commissioner. At a minimum, twelve of the fourteen members of the Advisory Committee, including the Committee Chair, shall be appointed by the Commissioner and one member shall be appointed each by the Temporary President of the Senate and Speaker of the Assembly. Members shall serve for three-year terms and may be reappointed for subsequent terms. The 13 members, in addition to the Chairperson who is designated by the Commissioner, shall include:
 - i. A Chairperson, who is a member of the Department and designated by the Commissioner;

- ii. At least three persons licensed and actively engaging in the practice of Medicine in New York State;
- iii. One person licensed and actively engaged in the practice of nursing as a nurse practitioner, or in the practice of midwifery in this state;
- iv. One person with expertise in health technology assessment or evidence based medical review who is preferably a health care professional licensed under Title Eight of the Education law;
- v. Three persons who shall be consumers or representatives of organizations with a regional or statewide constituency and who have been involved in activities related to health care consumer advocacy;
- vi. One person who is a representative of a hospital organization with a regional, national or statewide constituency;
- vii. One person who is a representative of a health insurance or managed care organization with a regional, statewide or national constituency;
- viii. One person who is a health economist;
- ix. One person with health care expertise who is appointed by the Temporary President of the Senate;
- x. One person with health care expertise who is appointed by the Speaker of the Assembly

IV. Meetings

a. Topic Selection for Committee Deliberations

The Department shall report to the Committee programmatic changes to benefits that do not rise to the level of a material change, as well as determinations of when sufficient medical evidence exists to warrant Committee deliberations. The topics and the criteria for the selection of such topics and items to be considered and reviewed by the Committee shall be guided by the following principles as set forth in Social Services Law Section 365-d (5). The Department shall utilize the following criteria to help guide its work in selecting topics and topic items to be brought before EBBRAC for their review, deliberation, and the rendering of an advisory recommendation. The Department shall be solely responsible for determining and selecting the topics and items that are to be referred to Committee for their consideration and review.

b. For the purposes of item and topic selection:

A “Material Change” to the Medicaid program for the purposes of EBBRAC topic review are changes that:

- i. require a coverage modification, be it an enhancement or reduction, to an existing Medicaid benefit,
- ii. establish a new benefit, or
- iii. eliminate a current benefit.

Exclusions of Topics that shall not be brought before the Committee for their consideration, are if it:

- i. does not have a sufficient body of evidence to warrant Committee deliberation,
- ii. is considered to be “experimental and investigational” by Medicare,
- iii. does not meet the one-million-dollar gross threshold (\$1,000,000) or does not meet the five percent (5 %) utilization by the targeted New York State

- Medicaid population,
 - iv. has a United States Preventative Task Force (USPSTF) A or B grade recommendation,
 - v. is a covered service mandated by statute or regulation,
 - vi. is covered by Medicare and the Department has determined to mirror the Centers for Medicare and Medicaid Services (CMS) benefit criteria,
 - vii. is an urgent or time-sensitive benefit decision, as determined by the Department, or
 - viii. is an expansion of a profession-specific scope of practice of an already covered service.
- c. A “New Technology” for the purposes of EBBRAC topic review is a Federal Drug Administration (FDA) cleared or approved device or procedure not currently or similarly covered by the State Medicaid program that:
- i. is used to promote or improve health outcomes, and
 - ii. is used to prevent, diagnose, or treat a disease or illness.

Exclusions of topics that shall not be brought before the Committee for their consideration, are if it:

- i. does not have a sufficient body of evidence to warrant Committee deliberation,
 - ii. is considered “experimental and investigational” by Medicare, does not meet the one-million-dollar gross threshold (\$1,000,000) or does not meet the five percent (5%) utilization by the targeted New York State Medicaid population,
 - iii. is a covered service mandated by statute or regulation,
 - iv. is covered by Medicare and the Department has decided to mirror CMS benefit criteria, or
 - v. is an urgent or time-sensitive benefit decision, as determined by the Department
- d. Scheduling

Committee meetings are conducted in Albany, New York or New York, New York. The Department shall post a notice of any meeting and the agenda of such meeting on its web site no later than forty-five days prior to the date of a scheduled meeting. The agenda and supporting documentation shall be sent to each Committee member at least seven days prior to a scheduled meeting for their review and preparation. Such notice shall include a description of the proposed health technology or service to be reviewed, the conditions or diseases impacted by such health technology or service, the proposals to be considered by the Committee, and the systematic evidence-based assessment prepared in accordance with Social Services Law Section 365-d (5). Committee meetings shall be held approximately two to three times in each calendar year.

A meeting summary and minutes, including the list of speakers that came before the Committee, deliberations, and recommendations of the Committee, shall be prepared by the Department of Health program staff for distribution to Committee members. After such meeting summary and minutes have been adopted by the Committee, they shall be posted on the Department’s website within ten days after such meeting has concluded or as soon as practicable.

e. Quorum

Each Committee meeting requires that a quorum of members must be present at a duly constituted meeting with proper notice given to conduct public business. A quorum consists of a majority of the whole number of members who are in each other's presence or by-videoconferencing.

f. Attendance

As each meeting of the Committee requires a quorum to conduct public business, in accepting an appointment to the Committee, members commit themselves to regular attendance at the scheduled meetings. Meeting dates shall be scheduled sufficiently in advance to allow for requisite planning and scheduling for attendance by Committee members. Members unable to attend a meeting must notify the Commissioner or his or her designee prior to the meeting. Substitute members are not permitted. It is expected that each member should attend a majority of scheduled Committee meetings within the calendar year. Failure to attend a majority of meetings may result in removal from the Committee. New members shall be appointed to fill any vacancies in accordance with these bylaws.

g. Conduct of Meetings

Committee meetings shall be conducted by the Chairperson or designee who is a member of the Committee. Every member of the Committee has one vote, and voting shall take place while the meeting is convened. The Department, according to law, shall provide video or audio access to all Committee meetings through the Department's website. The Committee shall not present its recommendations as the official policy of the State as it is an Advisory Committee. Confidential financial information shall only be presented or discussed during executive session. Members shall not release information that is made available to them by virtue of their participation on the Committee.

h. Public Comment

With prior notice to the Department, any interested party may request and may be permitted to provide oral comments or make a presentation to the EBBRAC during a public comment segment of the meeting on any item under consideration by the EBBRAC at that meeting. Individuals interested in providing public comments to the EBBRAC may submit a request to the Department at least five days in advance of a meeting to be added to the agenda. Before a request to provide public comment is granted, individuals shall be required to divulge any financial relationships which may influence their comments. Before an individual is permitted to provide public comment, the Chairperson shall require that the individual attest as to the accuracy of the information on financial relationships provided. Individuals granted permission to address the EBBRAC shall be notified of their inclusion on the public comment list when the list is deemed complete. The public comment period shall be at the beginning of the meeting. Up to seventy-five minutes may be devoted to public comments on issues to be considered by the EBBRAC. If multiple speakers are proposing to

address the same issue with the same point of view, and there is insufficient time to include all speakers, an individual may provide a brief written statement.

i. Decision Making

Every EBBRAC member has one vote, and voting shall take place while the meeting is convened. Committee recommendations may be adopted by consensus, with adoptions made by majority vote if the Chairperson deems such a vote necessary.

i. Decision Making Process and Notice

1. After the Committee has duly deliberated on each matter that has been placed on the EBBRAC agenda, the Committee members shall vote to either approve, modify, or deny such matter. Such advisory decision shall detail the recommended change in coverage of a health technology or services that has been brought before the Committee to include, change, or eliminate a health technology or service from the Medicaid program.
2. For all health technologies or services selected for review by the Department, the Department shall conduct or commission a systematic evidence-based assessment of the health technology or service's safety and clinical efficacy. Such assessment shall use established systematic review elements, study quality assessment, and data synthesis. Upon completion, the systematic, evidenced-based assessment shall be made available to the public.
3. The deliberations and recommendations of the Committee shall be based on a review of the oral and written evidence presented to the Committee, including the clinical effectiveness, patient outcomes, impact on a risk and underserved populations, and safety of such items under consideration and the systematic evidenced-based assessment cited above in sub-paragraph two of these Bylaws. The Committee may review previous recommendations of the Committee as new evidence becomes available and permit oral presentations and the submission of new evidence at future committee meetings.
4. The Commissioner shall provide notice of any coverage recommendations developed by the Committee and make such information and recommendations developed by the Committee available on the Department's website. Such public notice shall include: a summary of the deliberations of the Committee; a summary of the positions of those making public comments at such meeting and any safety and health outcomes data submitted by such interested party; the response of the Committee to those comments, if any; the clinical evidence upon which the Committee bases its recommendations; and the findings and recommendations of the Committee, including a final evidence-

based systematic assessment.

j. Commissioner's Final Recommendation

The Commissioner shall provide public notice on the Department's website of the Committee's recommendations and the Department's final determination, including: the nature of the determination; an analysis of the impact of the Department's determination on the State Medicaid plan populations and providers; and the projected fiscal impact to the State's Medicaid program. In arriving at its final recommendation, the Department may alter or revoke the advisory recommendations of the EBBRAC.

V. Conditions of EBBRAC Membership

a. Requirements

Any EBBRAC member licensed in New York State is required to be in good standing. No EBBRAC member may have Medicaid or Medicare sanctions against them.

b. Conflicts of Interest and Financial Disclosure

Members should exercise their duties and responsibilities as EBBRAC members in the public interest of the people of New York State, regardless of their affiliation with, or relationship to, any facility, agency or program, category of provider, or interest group. Members are required to disclose any interest, financial or otherwise, held by the member, his or her spouse/partner and minor children, in any entity that may have a direct interest in matters before the EBBRAC. Members should address questions regarding conflicts of interest or the appearance of conflicts of interest to Department staff, the Department's Ethics Officer, and the attorney for the EBBRAC.

i. Code of Ethics

No EBBRAC member should have any interest, financial or otherwise, direct or indirect, or engage in any business or transaction or professional activity, or incur any obligation of any nature, which is in substantial conflict with the proper discharge of his or her EBBRAC duties in the public interest. Members should also avoid the appearance of a conflict of interest.:

EBBRAC members must abide by and comply with the following Code of Ethics standards during their term of service on the Committee. At a minimum, such members shall not:

1. have any interest, financial or otherwise, direct or indirect, or engage in any business or transaction or professional activity, or incur any obligation of any nature, which is in substantial conflict with the proper discharge of his or her duties in the public interest. Members should also avoid the appearance of a conflict of interest.

2. accept employment which may impair his or her independence of judgment in the exercise of his or her official Committee duties.
3. accept employment or engage in any business or professional activity which would require him or her to disclose confidential information which he or she has gained because of his or her official duties on the Committee.
4. Not disclose confidential information acquired by him or her in the course of his or her Council duties or use such information to further his or her personal interests.
5. use or attempt to use his or her official Committee position to secure unwarranted privileges or exemptions for himself or herself or others, including but not limited to, the misappropriation to himself, herself or to others of the property, services or other resources of the State for private business or other compensated non-governmental purposes.
6. engage in any transaction as representative or agent of the state with any business entity in which he or she has a direct or indirect financial interest that might reasonably tend to conflict with the proper discharge of his or her official duties on the Committee.
7. by his or her conduct, give reasonable basis for the impression that any person can improperly influence him or her or unduly enjoy his or her favor in the performance of his or her official Committee duties, or that he or she is affected by the kinship, rank, position or influence of any party or person.
8. A member should abstain from making personal investments in enterprises which he or she has reason to believe may be directly involved in decisions to be made by him or her or which would otherwise create substantial conflict between his or her duty in the public interest and his or her private interest.
9. A member should endeavor to pursue a course of conduct which will not raise suspicion among the public that he or she is likely to be engaged in acts that are in violation of his or her trust.
10. No Committee member nor any firm or association of which such person is a member nor any corporation where a substantial portion of stock is owned or controlled directly or indirectly by such member, should sell goods or services to any person, firm, corporation or association which is licensed or whose rates are fixed by the state agency in which such Committee member serves or is employed.
11. Committee members must report all legislative and or lobbying contacts regarding any issue or decision under the purview of the Committee or from an agent or representative of an entity directly affected by Committee activity and employment status changes to the Commissioner or his or her designee to avoid any actual conflicts of interest or the appearance of any conflicts of interest.
12. Committee members may consult with medical/clinical peers for their professional expertise on an as needed basis, however, members must report to the Chair any contacts with private industry intended to influence the member in carrying out his or her duties on the Committee or intended to influence a decision of the Committee. Failure to do so may result in removal from the

Committee.

13. Committee members must complete the Departmental Ethics Training for Members of Advisory Boards and Councils within three months of beginning Committee service, or within three months of the Ethics Training becoming available. In addition, such members of EBBRAC must sign a statement, under oath, that they will not intentionally violate any of the conflict of interest or prohibited financial interest provisions provided for in Public Officers Law sections 73 and 74 and Article IV of these Bylaws, as it relates to their activities associated with their duties and work with regard to the Committee.

ii. Financial Conflicts of Interest

During the period of time of Committee membership, no Committee member may have a prohibited financial interest with any entity that has a direct interest in matters before the Committee. Such financial interests shall include, but not be limited to, the kinds of financial interests or conflict of interest relationships that are specified in Public Officers Law sections 73 and 74 and by Article IV of these Bylaws. Members appointed to the Committee agree to adhere to and follow the advisory ethics and financial disclosure opinions, directives, determinations, and decisions made and rendered by the Department of Health, made in consultation with the New York State Joint Commission on Public Ethics, as it relates to their activities associated with their duties and work with regards to the Council.

EBBRAC members must disclose any “financial interest” or “professional or personal affiliations” with any entity or person(s) that may have a direct interest in matters before the Committee, including, but not limited to healthcare products, services, and technologies

Such a “financial interest” may include, but is not limited to:

1. Owning stocks, bonds, options or other securities (excluding mutual funds and blind trusts);
2. Employed by, acting as a consultant or under contract, regardless of compensation
3. Receiving compensation for consultant services or speaker bureaus;
4. Receiving grants or other funding from entities interested in matters before the Committee;

Such a “professional or personal affiliation” may include, but is not limited to:

5. Holding a position in an advisory capacity, regardless of compensation
6. Speaking in support of a particular entity or product, regardless of compensation.
7. Accepting gratuities for professional or education activities;
8. Holding a leadership position within an organization that has an interest in matters before the Committee, regardless of

- compensation
9. Informal relationships with the potential to influence the Committee; or
 10. The Committee member's spouse, or a first degree relative or his/her spouse that has a financial, professional, or personal affiliation with an entity or person(s) that may have a direct interest in matters before the Committee.
 11. Accepting a gift or gifts totaling more than \$15 in value from a company or its representative. Gifts include but are not limited to money, services, loans, travel, lodging, meals, refreshments, and entertainment. Directing a gift to a third party is not permitted. EBBRAC members may accept complimentary attendance, including food or beverage, at an event sponsored by a company only if all of the following criteria are met:
 - a. the event is a professional development or educational program; and
 - b. it is not reasonable to infer that the event is intended to influence the EBBRAC member in carrying out his or her EBBRAC duties; and
 - c. it is not reasonable to infer that acceptance would influence the member in carrying out his or her EBBRAC duties and
 - d. complimentary attendance and food and beverage are offered to all attendees of the program;
 - e. the member may provide notice to the Chairperson of his or her intent to attend the program in advance of attendance; and
 - f. the member provides information of all such events prior to each meeting, concurrent with the submission of the EBBRAC Conflict of Interest Statement referenced in Section V(b)(iii) of these Bylaws.
 12. The Chairperson, in consultation with the Department, reserves the right to prohibit attendance where he or she concludes that attendance would create a conflict of interest or the appearance of a conflict of interest.
 13. Working on a grant paid by a corporation or participating in clinical trial(s) or grant(s) for which compensation is paid directly to the EBBRAC member by the corporation. EBBRAC members shall notify the Chairperson of participation in any company-funded clinical trials or grants in which the EBBRAC member is not paid directly by the corporation or organization.

iii. Financial Disclosures and Recusal Requirements

Prior to appointment to the Committee, and annually thereafter, members are required to disclose any interest, financial or otherwise, held by the member, his or her spouse/partner and minor children, in any entity that may have a direct interest in matters before the Committee.

If a conflict of interest or appearance of a conflict of interest arises that is not due to a financial interest held by a member, the member must recuse him or herself from participating in the relevant presentation, discussion

and the vote. The Chairperson, in consultation with the Department, has the authority to determine whether and when recusal is required, or whether the conflict of interest can be avoided only by divestiture or resignation from the Committee.

A conflict of interest caused by a financial interest held by a member may not be remedied by recusal. The member must either divest himself or herself of the conflicting financial interest within a reasonable time set by the Chairperson, in consultation with the Department, or resign from the Committee. If a member intends to divest himself or herself of such interest but has not done so before the next Committee meeting, the member may be permitted to recuse himself or herself entirely from one meeting.

If a conflicting financial interest not reported by a member has been reported by a third party, the member may provide information or evidence to the Chairperson, who shall determine, in consultation with the Department, and consistent with these Bylaws, whether recusal, divestiture or resignation is required.

iv. Failure to Disclose

The failure of a member to accurately report a conflicting financial interest, and/or, to recuse himself or herself from a discussion, vote, or meeting when a conflict of interest exists, may result in removal from the Committee.

The Chairperson, in consultation with the Department, shall determine whether the member's failure to report a conflicting interest necessitates recusal or removal from the Committee.

A member's failure to resign or divest himself or herself of such interest if so, directed by the Chairperson shall result in removal from the Committee.

The Committee Chairperson, in consultation with the Department, shall have the authority to determine, consistent with these Bylaws, whether an interest disclosed by a member gives rise to a conflict of interest and, if so, whether it necessitates recusal, divestiture, or a recommendation to the Commissioner for removal from the Committee.

VI. Administration of the Board

a. Terms

Each EBBRAC member shall serve for a three-year term. EBBRAC members may be reappointed upon the completion of their terms.

b. Resignation

A member may voluntarily resign prior to the completion of their term by notifying the Commissioner or his or her designee within a minimum of 90 days prior to their resignation date.

c. Removal from the Board

A member may be removed from the Committee for a knowing and intentional violation of any provision of these bylaws, or for any other reason at the discretion of the Commissioner.

d. Vacancies

Vacancies resulting from a Committee member's resignation, non-renewal, or the completion of term shall be filled, upon appointment by the Commissioner, with candidates who meet the requirements of the membership.

e. Staff Support and Cooperation of State Agencies

Department program staff shall be available to assist the Committee in its work and that of the Committee Chairperson. Technical assistance and staff support shall be provided by the Department.

f. Reimbursement

Members of the EBBRAC shall receive no compensation but shall be entitled to reimbursement for any necessary travel expenses incurred in connection with the performance of their duties, at levels in accordance with NYS approved amounts for travel expenses including transportation, meals and lodging costs required to attend EBBRAC meetings.

g. Amendments to these EBBRAC Bylaws

The Department may propose amendments to these Bylaws to the EBBRAC. Amendments to the Bylaws shall be made when recommended by the Committee and approved by the Commissioner or his or her designee. The Bylaws shall be reviewed at least annually.