

THE BRODY SCHOOL OF MEDICINE AT EAST CAROLINA UNIVERSITY COMPLIANCE PROGRAM

I. STATEMENT OF PURPOSE

The primary purpose of the Office of Compliance at The Brody School of Medicine (“BSOM”) is to aid in fulfilling the goals and mission of BSOM which include education of future physicians, improvement of the health status of citizens in eastern North Carolina, and research to advance patient care. The Office of Compliance enhances this mission by ensuring that BSOM conducts its patient care activities, research, and operations in an ethical and law-abiding manner. The Office of Compliance is committed to building and maintaining a culture of compliance that encourages employees, students, contractors, and faculty to conduct all BSOM operations with honesty and integrity.

The Compliance Program provides a framework for BSOM compliance with applicable healthcare state and federal laws and regulations in areas including but not limited to government and private payor reimbursement, the Federal Anti-kickback Statute, the Prohibition on Physician Self-Referrals (Stark law), conflict of interest disclosure, and research. The Compliance Program is not intended to set forth every program and practice that is designed to effect BSOM compliance but rather to provide a framework that will guide the overall compliance effort of BSOM.

II. OFFICE OF COMPLIANCE OVERSIGHT

A. Director of Compliance

The Office of Compliance at BSOM is responsible for overseeing the creation, implementation, and monitoring of mechanisms that ensure compliance with applicable healthcare state and federal laws and regulations. The Director of Compliance (the “Director” or “Director of Compliance”) guides and oversees the Office of Compliance including the design, implementation, monitoring and assessment of BSOM-wide compliance activities.

The Director reports directly to the Chief Legal Counsel for BSOM. Because the responsibility of the Office of Compliance includes oversight of all levels of BSOM administrative, research and clinical operations, and over all BSOM employees, faculty, and administrative officials, the Director, when necessary and appropriate, shall provide reports to the Dean for BSOM, the Vice Chancellor for Health Sciences, ECU Office of Internal Audit, and the ECU Board of Trustees.

Responsibilities of the Director of Compliance include:

- Developing a comprehensive compliance program for BSOM;
- Identifying regulatory compliance obligations of BSOM, its administration, and employees;
- Providing guidance and assistance, in consultation with BSOM Chief Legal Counsel, in the preparation of written guidelines, policies, procedures, and standards of conduct on specific legal and regulatory issues involving medical, business, research and administrative practices at BSOM;
- Developing and overseeing the implementation of educational training programs;
- Developing effective lines of communication throughout BSOM to enhance effectiveness of the Compliance Program;
- Coordinating investigations of credible information related to potential non-compliance involving BSOM administration or employees;
- Monitoring of operations to identify and rectify barriers to compliance; and
- Recommending corrective action and/or appropriate discipline with respect to incidents of non-compliance.

B. Compliance Committee Oversight

The Compliance Committee (“CC”) is responsible for oversight of the Compliance Program. The duties of the CC include:

- Annual analysis of the effectiveness of the BSOM Compliance Program;
- Review and preliminary approval of all compliance policies and procedures to be submitted to the Dean for BSOM or Vice Chancellor for Health Sciences for final approval;
- Recommendations and review of an annual risk assessment tool which will be used by the Director in determining priorities for the Office;
- Recommendations for Program improvement; and
- Review of compliance initiatives as recommended by the Office of Compliance.

The Director of Compliance serves as Chair of the CC. Members of the CC consist of the following:

1. Members with no term limits:
 - Senior Associate Dean for Operations
 - Associate Dean for Clinical Affairs
 - Assistant Dean for Operations
 - BSOM Chief Legal Counsel
 - Chief Financial Officer
 - Director of Risk Management

- Associate Director of Risk Management
 - Billing Compliance Manager
 - Executive Director of the Institutional Review Board or designee
 - Director of Clinical Finance
 - Privacy Officer
 - Nursing leadership designee
 - Group Practice Administrator
 - Executive Director of the University's ECU Office of Internal Audit and Management Advisory Services
 - Chairperson of the Institutional Animal Care and Use Committee or designee
2. The following members will be appointed by the Dean for BSOM for two year terms. Members may be appointed for up to two additional consecutive terms. If a voting member is unable to complete a term on the CC, the Dean for BSOM will appoint a replacement. The replacement will serve the remaining portion of the term and may then be appointed for up to two subsequent consecutive terms. These appointed members shall include the following:
- Two department chairs (one Clinical and one Basic Science)
 - Three faculty members-at-large (with at least one Clinical and one Basic Science at all times)
 - Two clinical department administrators
3. Permanently invited guests with voice but no vote:
- UHS Chief Audit and Compliance Officer
4. Resource member with voice but no vote:
- The Committee Chair may appoint a resource member with voice but no vote.

The CC meets on a monthly basis. A summary of items addressed and actions taken at each meeting will be recorded and retained by the Director. The CC is required to make periodic reports to the ECU Physicians Practice Plan Board, BSOM Executive Committee, the Brody Council, and the BSOM faculty when necessary. The Assistant to the Director of Compliance will maintain contemporaneous minutes of each meeting.

III. COMPLIANCE EDUCATION AND TRAINING

The BSOM is committed to providing education and training that will ensure compliance and emphasize BSOM's commitment to legal and ethical conduct. The Director of Compliance is responsible for developing, coordinating, implementing, and monitoring training and education programs to aid BSOM employees (including BSOM leased employees and independent contractors providing services on behalf of BSOM, hereinafter included in the term

“employees”) in maintaining compliance with relevant laws, regulations, policies, and guidelines.

Each new BSOM employee and contractor shall be required to complete initial compliance training which shall include but not be limited to information related to: (1) the BSOM Compliance Program; (2) Billing and Reimbursement (including the requirements set forth under the ECU Physicians Group Practice Standards for Documenting and Billing Medical Professional Services (the “ECU Physicians Standards”) for all billing providers); (3) Medicare/Medicaid fraud and abuse; (4) Research compliance; (5) the Federal Prohibition on Physician Self-Referral (“Stark”); and (6) the False Claims Act and qui tam provisions (both federal and state laws).

In addition, each new BSOM employee shall be required to read the BSOM Code of Conduct and sign an attestation related to the BSOM Code of Conduct. All new employees shall be given a copy of the BSOM Code of Conduct. Such attestation shall be forwarded to each employee’s supervisor or contact person. In addition, every current BSOM employee shall be required to complete an annual attestation reaffirming his or her understanding of the BSOM Code of Conduct. Each Department Chair or Director shall be required to forward the “Confirmation of Receipt of Code of Conduct Annual Attestation Statement” to the Office of Compliance as directed by the Director of Compliance which verifies that all employees within such Department Chair’s or Director’s department have completed the required attestation.

The Office of Compliance shall also offer, organize, and facilitate various types of education and training to current employees. Each BSOM provider with billing privileges shall be required to undergo annual training related to the ECU Physicians Standards. In addition, as new developments or concerns arise, current employees may be required to undergo additional training and education, as determined by the Director of Compliance in consultation with the Vice Chancellor for Health Sciences, Dean for BSOM, or other personnel as necessary, and the CC. In addition, the Office of Compliance shall provide periodic notifications, newsletters, and other such types of communications regarding compliance to all BSOM employees.

Training attendance shall be documented, and the Office of Compliance shall maintain all records of attendance at each training session performed by the Office of Compliance. Each department shall be responsible for maintaining records of attendance for compliance training that may be conducted by other parties and copies of these records shall be forwarded to the Office of Compliance. Failure to attend mandatory training may result in a recommendation by the Director of disciplinary action to the applicable department chairperson or relevant supervisor, including the potential revocation of billing privileges pending training completion as per ECU policy.

IV. COMPLIANCE RISK ASSESSMENT

The Office of Compliance shall complete a risk assessment of BSOM compliance issues on an annual basis. The purpose of a risk assessment is to help identify significant compliance risk areas relevant to BSOM, and to allocate compliance resources to monitor those areas which pose greater risk to the BSOM. The following are examples (but are not all inclusive) of factors that may be considered in performing the annual risk assessment:

- Consultations held with management personnel including the Vice Chancellor for Health Sciences, Dean for BSOM, Senior Associate Dean for Operations, Chief Financial Officer, Department Chairs, Medical Director, Clinical Administrators, Associate Dean for Research and Graduate Studies, Chief Legal Counsel, ECU Office of Internal Audit, and other pertinent individuals, committees or workgroups at BSOM;
- Results from any previous compliance monitoring activities;
- Inquiries from the Compliance Hotline;
- Input from the CC;
- Published OIG initiatives;
- Results of any CMS audits;
- BSOM provider profiling results;
- Federal enforcement activity; and
- Federal regulatory issuances or guidance.

Results of the annual risk assessment shall be shared with the CC, and, as necessary, the Vice Chancellor for Health Sciences, Dean for BSOM, Senior Associate Dean for Operations, ECU Office of Internal Audit, and the Faculty Practice Plan Board.

V. COMPLIANCE MONITORING AND RESPONSE TO IDENTIFIED ISSUES

The Office of Compliance shall implement, facilitate and/or oversee various monitoring systems that are reasonably designed to detect noncompliance and criminal conduct in order to achieve compliance with the policies and procedures of East Carolina University (hereinafter "ECU" or "University"), federal and state laws and regulations, and other guidance as applicable. Monitoring shall be performed with respect to those relevant areas of BSOM operations as identified in the annual risk assessment and any other areas as determined by the Director. The Director shall also work in collaboration with the ECU Office of Internal Audit with respect to coordination of monitoring activities and the identification of potential areas for monitoring and oversight. Policies and procedures may be developed, as necessary, regarding the monitoring process. Results of such monitoring activities shall be reported to the CC and other relevant BSOM personnel as necessary. Results of monitoring activities may also be directly reported to BSOM Chief Legal Counsel and/or

the ECU Office of Internal Audit for ECU, as necessary (note that both of these entities are also Members of the Compliance Committee, and thus would receive notification through that medium as well).

A. Provider Documentation, Coding, and Billing Monitoring

The Office of Compliance shall conduct routine, random prospective reviews of billing claims data from a representative sample of medical and billing records for a designated period to assess compliance with established standards of practice for teaching physician documentation, coding, and billing. A focused review may target specific providers, specialties, CPT codes, Evaluation and Management codes, or any other criteria as established by the Director. The Office of Compliance shall specifically examine records for compliance with Medicare, Medicaid, TRICARE, and other third party billing requirements, as well as the ECU Physician Standards.

Following this review, results shall be reported to the applicable provider and coder who may have coded such physician's documentation. Education shall be performed at such time regarding any documentation deficiencies noted, or methods on how to improve documentation. In addition, if documentation deficiencies are found, an additional review will be performed within 90 to 120 days following such education session to determine if deficiencies continue to exist. Any claims that are identified with incomplete or inaccurate documentation shall not be submitted for payment to any third party payor. Periodic reports shall be provided to the CC regarding the results of billing claim data reviews. Serious or recurrent billing deficiencies will be subject to a specific corrective action plan.

In the event a pattern of documentation, coding or billing errors is identified, the Office of Compliance may perform a retrospective review related to such error, in consultation with BSOM Chief Legal Counsel, as necessary. The time period for retrospective review, along with the number of claims to be reviewed shall be determined by the Director in consultation with BSOM Chief Legal Counsel, as necessary. Any identified overpayment amounts detected as a result of billing monitoring by the Office of Compliance shall be promptly refunded to the appropriate third party payor and proof of such refund shall be provided to the Director.

In the event of failure to properly follow and maintain compliance with the ECU Physician Standards and applicable law and regulations, faculty and staff may be subject to appropriate disciplinary action, up to and including termination from employment, in accordance with ECU policy, as may be recommended by the Director in consultation with BSOM Chief Legal Counsel, and as determined by the applicable Department Chair, Dean for BSOM, and Vice Chancellor for Health Sciences.

B. Contract Reviews

The Office of Compliance shall routinely review every contract entered into between BSOM and any third party provider, pharmaceutical company/device manufacturer, medical supply company, or any other type of entity as determined by the Director. The Director shall consult the BSOM Chief Legal Counsel as necessary regarding any potential Stark, Federal Antikickback, or other healthcare compliance issues that may be identified related to those contract reviews. The Office of Compliance shall maintain a database of all such contracts. The Office of Compliance shall ensure that all such outside contracting entities have not been debarred, excluded, suspended or otherwise determined to be ineligible to participate in any federal healthcare program.

C. Research Monitoring

BSOM is committed to performing research in a manner that is compliant with applicable federal and state regulations, Good Clinical Practices, ECU policy, and research protocol. Furthermore, the continued safety of our patients as study participants and our animal study subjects is of paramount importance. In furtherance of these ideals, the Office of Compliance shall establish a Research Monitoring Program (“RMP”) to monitor compliance of research performed at BSOM with applicable federal and state regulations, Good Clinical Practices, ECU policy, and research protocol. Among other functions, the RMP will perform random protocol reviews and targeted reviews of selected protocols based on degree of risk associated with such protocol (e.g., type of study, vulnerable study population, expected adverse events, history of noncompliance, etc.). The RMP will also monitor compliance with respect to billing for clinical trials. Educational sessions with the investigator and other staff, as necessary, will be held following such review. Any deficiencies found will be subject to a corrective action plan, and the applicable investigator shall be responsible for the timely and complete resolution of any noted deficiencies. Periodic reports of RMP results shall be provided to the CC, and any other relevant BSOM or ECU personnel as necessary. Failure of faculty and staff to adhere to research protocol, applicable federal and state regulations, and ECU policy in the performance of research at BSOM may result in disciplinary action, up to and including termination of employment, in accordance with ECU policy, as recommended by the Director in consultation with BSOM Chief Legal Counsel and as determined by the applicable Department Chair, Dean for BSOM, and Vice Chancellor for Health Sciences.

D. Ad Hoc Monitoring

The Office of Compliance shall perform monitoring of any other areas as identified by the Director or the CC. Areas for additional monitoring may be identified based on the OIG Work Plan, OIG Advisory Opinions, any recent regulatory enforcement initiatives or settlements, Compliance Hotline calls or inquiries, or other risk areas identified at BSOM. Such ad hoc monitoring shall be performed in consultation with Chief Legal Counsel of BSOM and/or ECU Office of Internal Audit as necessary. Results of all such monitoring shall be reported to the CC; copies of reports may also be directly provided to BSOM Chief Legal Counsel and/or ECU Office of Internal Audit (note that both of these entities are also Members of the Compliance Committee, and thus would receive notification through that medium as well).

E. Conflicts of Interest and Conflicts of Commitment

1. Conflicts of Interest

Per ECU policy, all faculty and EPA non-faculty shall avoid conflicts of interest that have the potential to adversely affect the University's interests, to compromise objectivity in carrying out University responsibilities, or otherwise to compromise the performance of University responsibilities. (ECU Faculty Manual, Appendix I-3.) As such, every faculty member and EPA non-faculty member is required to disclose annually for both him/her and his/her immediate families the extent of their relevant external activities and relationships and their financial holdings that are related to such employee's University activities. To facilitate this disclosure, each faculty and EPA non-faculty member must complete the "Annual Faculty/Professional Staff Disclosure Form" (the "Conflicts Disclosure Form") pursuant to the procedure set forth in the ECU Faculty Manual, Appendix I-5. Further disclosure may be required depending on the information disclosed. Mid-year revisions or updates to the Conflicts Disclosure Form are required in the event of a significant change in the individual's affairs that may lead to or may be perceived to lead to a conflict with such individual's University activities. For additional details related to the University's policy regarding conflicts of interest, please refer to the ECU Faculty Manual, Appendix I.

The Office of Compliance shall aid in the monitoring and resolution of disclosed conflicts of interest. In addition, each Department Chair or Director is required to forward to the Office of Compliance the "Annual Report of Faculty/Staff Compliance with ECU Conflict of Interest and

Commitment Policy” on an annual basis as directed by the Director of Compliance.

2. Conflicts of Commitment

Per ECU policy, all faculty and EPA non-faculty employees shall devote their primary professional loyalty, time, and energy to their teaching, research, service, and where applicable, patient care at the University. Outside activities and financial interests must be arranged to avoid interference with the primacy of these commitments. (ECU Faculty Manual, Appendix I-3.)

The University acknowledges the benefits of participation of faculty and other professional staff members in external professional activities for pay; these benefits range from enhancement of employee capabilities to societal benefits, including economic development through technology transfer. (ECU Faculty Manual Part VI-15). However, such external professional activities for pay are to be undertaken only if they do not: (i) create a conflict of commitment by interfering with the obligation of the individual to carry out all primary university duties in a timely and effective manner; or (ii) create a conflict of interest vis-à-vis the individual’s status as an employee of the University; or (iii) involve any inappropriate use or exploitation of University resources; or (iv) make any use of the name of The University of North Carolina or any of its constituent institutions for any purpose other than professional identification; or (v) claim, explicitly or implicitly, any University or institutional responsibility for the conduct or outcome of such activities. (ECU Faculty Manual Part VI-15).

A faculty or other professional staff member who plans to engage in external professional activities for pay shall complete the “Notice of Intent to Engage in External Professional Activity for Pay” (hereinafter “Notice of Intent”) which shall be filed with the Department Chair or applicable supervisor. A separate Notice of Intent shall be filed for each such activity in which an employee proposes to engage. The Notice of Intent shall be filed not less than 10 calendar days before the date the proposed external professional activity for pay is to begin, except in exceptional circumstances. For additional procedures relating to the Notice of Intent, please refer to the ECU Faculty Manual, Part VI.

F. Corrective Action Plans

In the event any incident of noncompliance has been confirmed by the Director of Compliance, a corrective action plan may be required to be developed as determined by the Director in collaboration with the affected individual(s), the applicable Department Chair, and the Director of

Compliance. The corrective action plan will focus on the actions that will be necessary to correct the incident(s) of noncompliance, and the processes to be established to prevent future similar occurrences. The Director of Compliance shall submit the recommendations to the CC for review and approval. The Director of Compliance shall notify and meet with the Department Chair, the affected individual(s) and explain the corrective action to be implemented. The corrective action plan may include one or all of the following elements:

- Investigation findings and supporting data
- Specific areas or operations affected
- Any recommended changes to policies or procedures
- Any recommendations for education
- Further monitoring that may be required
- Timeline of required action
- Recommendations for disciplinary action

The Department Chair and the affected individual(s) shall provide written notification to the Director once all necessary corrective action(s) has been taken.

VI. COMPLIANCE REPORTING SYSTEM

Everyone working for or on behalf of BSOM has an obligation to be aware of the rules and regulations that govern their work and an obligation to seek answers and guidance when unsure about a course of action or situation. Employees may report or discuss suspected violations of the Code of Conduct or the Program with their immediate supervisor or administrator, or with the Director of Compliance or via the Compliance Hotline. Non-employees should contact the individual with whom they traditionally interact at the BSOM.

Everyone is encouraged to work with their supervisor, administrator or contact person in evaluating and reporting potential violations. However, the BSOM guarantees the right of confidentiality to anyone and to anonymously discuss or inquire about compliance issues or report suspected violations directly to the Director of Compliance or anonymously via the Compliance Hotline. The toll-free Compliance Hotline does not have caller ID. A summary of each confidential report shall be provided to the ECU Office of Internal Audit, and to BSOM Chief Legal Counsel and/or Director of Risk Management, as necessary.

Contact Numbers:

Compliance Hotline (toll free) (866) 515-4587
Director of Compliance (252) 744-5200
BSOM Chief Legal Counsel (252) 744-3013
ECU Office of Internal Audit (252) 328-9025

There will be no reprisals for inquiries or good faith reporting of actual or possible violations of the Code of Conduct or the Program. The BSOM will protect, to the fullest extent allowed by law, the identity of anyone reporting a violation. All reports will be investigated with protection of the identity of the subject(s) of the investigation to the fullest extent possible.

It is a serious violation of the BSOM's policy to falsely report a Code of Conduct violation or to retaliate or attempt to retaliate against anyone who makes a good faith report of a suspected or known violation.