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 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), and clinical 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. Chief Compliance Officer

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 Chief Compliance Officer (the "CCO") guides and oversees the Office of Compliance including the design, implementation, monitoring and assessment of BSOM-wide compliance activities.

The CCO reports directly to the Dean and Vice Dean of the BSOM. Because the responsibility of the Office of Compliance includes oversight of all levels of BSOM administrative and clinical operations, and over all BSOM employees, faculty, and administrative officials, the CCO, when necessary and appropriate, shall provide reports to the ECU Physicians Board of Directors, Vice Chancellor of Health Sciences and the ECU Board of Trustees.

Approved by Paul R.G. Cunningham, MD, FACS
Dean, Brody School of Medicine
October 3, 2012
Responsibilities of the Chief Compliance Officer 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 the Office of the University Attorney, in the preparation of written guidelines, policies, procedures, and standards of conduct on specific legal and regulatory issues involving medical, business 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 noncompliance 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 or Vice Chancellor for Health Sciences for final approval;
- Recommendations and review of an annual risk assessment tool which will be used by the CCO in determining priorities for the Office;
- Recommendations for Program improvement; and
- Review of compliance initiatives as recommended by the Office of Compliance.

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

1. Members with no term limits:
   - Vice Dean, BSOM
   - Assistant Dean, Operations
   - Executive Director for ECU Physicians
   - ECU Physicians Chief Financial Officer
• Director of Risk Management
• Chief Compliance Officer
• Billing Compliance Manager
• Executive Director of the Institutional Review Board or designee
• Director of Clinical Financial Services
• Director of Nursing or designee
• Director of Health Information Management and Services
• Executive Director of the University's Office of Internal Audit and Management Advisory Services or designee

2. The following members will be appointed by the Dean 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 committee, the Dean 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)
• Two faculty members-at-large (with at least one Clinical and one Basic Science at all times)
• Two clinical department administrators

3. Resource members with voice but no vote:
• The Committee Chair may appoint a resource member with voice but no vote.
• Enterprise Risk Management Leadership or designee
• Office of the University Attorney representative

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

III. 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 Chief Compliance Officer is responsible for developing, coordinating, implementing, and monitoring training and education programs to aid BSOM faculty, staff, and contractors 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) 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); (2) Medicare/Medicaid fraud and abuse; (3) Research compliance; (4) the Federal Prohibition on Physician Self-Referral (“Stark”); and (5) the False Claims Act and Qui Tam provisions (both federal and state laws). In addition, each new BSOM employee and contractor shall be required to read the BSOM Code of Conduct and sign an attestation related to the BSOM Code of Conduct. All new employees and contractors shall be given a copy of the BSOM Compliance Program and the BSOM Code of Conduct.

The Office of Compliance shall also offer 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 Chief Compliance Officer in consultation with the Vice Chancellor for Health Sciences, Dean, 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 CCO of disciplinary action, depending on the severity of the circumstance, to the applicable department chairperson or relevant supervisor.

IV. 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 factors may be considered in performing the annual Risk Assessment:

- Consultations held with management personnel including the Vice Chancellor for Health Sciences, Dean, Vice Dean, Chief Financial Officer,
Department Chairs, Medical Director, Clinical Administrators, 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, Vice Dean, and the Faculty Practice Plan Board.

V. COMPLIANCE MONITORING AND RESPONSE TO IDENTIFIED ISSUES

The Office of Compliance shall implement a monitoring system that is reasonably designed to detect noncompliance and criminal conduct 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 CCO. 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 the Office of the University Attorney and/or the 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, prospective reviews of billing claim 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 CCO. The Office of Compliance may examine records for compliance with Medicare, Medicaid, and other third party billing requirements, as well as the ECU Physician Standards. Following this review, results shall be reported to the applicable Department Chair. The ECU Physicians Medical Director will receive a monthly summary report on
the provider reviews conducted and a copy of the provider review for any individual Department Chair.

For providers who do not earn a passing score, education shall be provided regarding any deficiencies noted and methods to improve documentation. In addition, for providers who do not earn a passing score, an additional review will be performed within three months following such education session to determine if deficiencies continue to exist. If a passing score is not earned on this additional (2nd) review, further education, remediation, and a third review will take place. If after three reviews, a provider does not earn a passing score the above actions will be taken as well as potential sanctions per ECU Physicians policies, ECU Physicians Credentialing plan, the ECU Physicians Clinical Faculty Compensation plan or other University policies and procedures as appropriate.

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 billing deficiencies will be subject to a specific corrective action plan.

In the event a particular documentation, coding or billing issue is identified, the Office of Compliance may perform a retrospective review related to such issue as necessary. The time period for retrospective review, along with the number of claims to be reviewed shall be determined by the CCO in consultation with the Office of the University Attorney as necessary. Any identified overpayment amounts shall be promptly refunded to the appropriate third party payor and proof of such refund shall be provided to the CCO.

Faculty and staff may be subject to appropriate disciplinary action, up to and including termination from employment for failure to properly follow and maintain compliance with the ECU Standards.

B. Contract Reviews

The Office of Compliance shall review every agreement 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 CCO. The CCO shall consult the Office of the University Attorney as necessary regarding any potential Stark, Federal Anti-kickback, or other healthcare compliance issues that may be identified related to those contract reviews. 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

The Office of Compliance shall establish a Research Monitoring Program ("RMP") to 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 accurately bill for clinical trials, and follow ECU policy in the performance of research at BSOM may result in disciplinary action, up to and including termination of employment.

D. Ad Hoc Monitoring

The Office of Compliance shall perform monitoring of any other areas as identified by the Chief Compliance Officer 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 the Office of the University Attorney and/or 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 the Office of the University Attorney and/or 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 affect adversely the University’s interests, to compromise objectivity in carrying out University responsibilities, or otherwise to compromise the performance of University responsibilities. As such, every BSOM faculty member and EPA non-faculty member is required to disclose annually for both him/her selves and 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 BSOM 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
University Policies, Rules, and Regulations and/or the Faculty Manual. 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.

The Director of Research Compliance, Division of Research and Graduate Studies is responsible for this Conflict of Interest Disclosure process, including monitoring and managing disclosed conflicts of interest. The Office of Compliance shall aid in monitoring and managing disclosed conflicts of interest within BSOM upon request of the Director of Research 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.

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. 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.

A BSOM faculty or other professional staff member who plans to engage in external professional activity 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.

F. Corrective Action Plans

In the event any incident of noncompliance has been confirmed by the Office of Compliance, a corrective action plan shall be developed in collaboration with the affected individual(s), the applicable Department Chair, and the Chief Compliance Officer. 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 Chief Compliance Officer shall submit the recommendations to the CC for review and approval. The Chief Compliance Officer 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 CCO once all necessary corrective action(s) has been taken.

VI. Reporting System

Everyone working for or on behalf of BSOM has an obligation to be aware of the rules and regulations that govern his/her 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, the Chief Compliance Officer, 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 his/her supervisor, administrator or contact person in evaluating and reporting potential violations. However, the BSOM provides the option to anonymously report suspected violations directly to the Chief Compliance Officer or anonymously via the Compliance Hotline. The toll-free Compliance Hotline does not have caller ID. A summary of each
anonymous or confidential report shall be provided to the Department of Internal Audit for the University, to the Office of the University Attorney, and Director of Risk Management, as appropriate.

Contact Numbers:
Compliance Hotline (toll free) (866) 515-4587
Chief Compliance Officer (252) 744-5200
Office of the University Attorney (252) 744-3013
Office of Internal Audit (252) 328-9025

There will be no reprisals for inquiries or good faith reporting of actual or suspected 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.

Paul R.G. Cunningham, MD, FACS
Dean, Brody School of Medicine
East Carolina University

10/12/2012
Date