LEGISLATIVE RESEARCH COMMISSION

PATHOLOGICAL MATERIALS COMMITTEE

NORTH CAROLINA GENERAL ASSEMBLY

REPORT TO THE 2013 GENERAL ASSEMBLY OF NORTH CAROLINA

JANUARY 2013

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TRANSMITTAL LETTER

January 8, 2013

TO THE MEMBERS OF THE 2013 REGULAR SESSION
OF THE 2013 GENERAL ASSEMBLY

The Legislative Research Commission herewith submits to you for your consideration its report and recommendations to the 2013 Regular Session of the 2013 General Assembly. The report was prepared by the Legislative Research Commission's Committee on Pathological Materials, pursuant to G.S. 120-30.70(1).

Respectfully submitted,

Senator Thomas M. Apodaca
Co-Chair Designee

Representative Timothy K. Moore
Co-Chair Designee

Co-Chairs
Legislative Research Commission

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LEGISLATIVE RESEARCH COMMISSION MEMBERSHIP

2011 – 2012

President Pro Tempore of the Senate
Senator Philip E. Berger
Co-Chair

Senator Thomas M. Apodaca
Acting Co-Chair

Senator Peter S. Brunstetter
Senator Linda D. Garrou
Senator Martin L. Nesbitt, Jr.
Senator Richard Y. Stevens

Speaker of the House of Representatives
Representative Thomas R. Tillis
Co-Chair

Representative Timothy K. Moore
Acting Co-Chair

Representative John M. Blust
Representative Justin P. Burr
Representative Mike D. Hager
Representative Edith D. Warren

STAFF
Bill Patterson, Research Division

Amy Jo Johnson, Research Division

Joseph Kyzer, Committee Clerk

Barbara Riley, Research Division

Susan Barham, Research Division

PREFACE

The Legislative Research Commission, established by Article 6B of Chapter 120 of the General Statutes, is the general purpose study group in the Legislative Branch of State Government. The Commission is co-chaired by the President Pro Tempore of the Senate and the Speaker of the House of Representatives and has five additional members appointed from each house of the General Assembly. Among the Commission's duties is that of making or causing to be made, upon the direction of the General Assembly, "such studies of and investigation into governmental agencies and institutions and matters of public policy as will aid the General Assembly in performing its duties in the most efficient and effective manner" (G.S. 120-30.17(1)).

The Legislative Research Commission authorized the study of Pathological Materials under authority of G.S. 120-30.17(1). The Co-chairs of the Committee were Senator Thom Goolsby and Representative Tom Murry. The full membership of the Committee is listed under Committee Membership. A notebook containing the Committee minutes and all information presented to the Committee will be filed in the Legislative Library.

COMMITTEE PROCEEDINGS

The Legislative Research Commission's Committee on Pathological Materials met two times after the 2012 Regular Session. The Committee's charge can be found at Appendix B. The following is a brief summary of the Committee's proceedings. Detailed minutes and information from each Committee meeting are available in the Legislative Library.

December 5, 2012

The Committee met on Wednesday, December 5, 2012, in Room 544 of the Legislative Office Building at 3:30 pm. Bill Patterson, Staff Attorney, Research Division, provided a summary of the Committee Authorization and an overview of the Committee's charge. He explained that the Committee is required under Legislative Research Commission (LRC) rules to transmit any final report with recommendations to the LRC Co-chairmen no later than January 4, 2013. Lastly, Mr. Patterson gave a summary of House Bill 795, "Patient Access to Pathological Materials," listed its sponsors, and reviewed its legislative history.

Hugh Tilson, North Carolina Hospital Association, presented a draft of best practices for hospitals and labs in North Carolina to ensure that the procedures utilized by interested parties to request patients' pathological materials are consistent with the regulations governing the retention of pathological materials (See Appendix E). Mr. Tilson explained that these draft principles are in compliance with federal regulations. Mr. Tilson expressed the Hospital Association's desire to work with those interested in gaining access to samples to ensure that attorneys and representatives get the information they need from those samples. After conversations with national experts, the Hospital Association's position is that the original samples should be stored on-site.

The next speaker was Dr. Shannon McCall, a pathologist at Duke University Medical Center. She gave a step-by-step explanation of how requests for pathological materials are handled at Duke. As the Quality Assurance Officer for the pathology practice at Duke University Medical Center, she explained that she was quite familiar with the federal regulations that govern the issues today. In addition, Dr. McCall provided handouts to the Committee regarding Duke's policies on pathological materials. Dr. McCall indicated that these policies reflect the best practices policies and procedures regarding the retention of pathological materials.

Dr. Kevin Smith introduced himself as a practicing pathologist in Charlotte, North Carolina, and the current president of the North Carolina Society of Pathologists. Dr.

Smith explained that the North Carolina Society of Pathologists, in conjunction with the North Carolina Medical Society, the College of American Pathologists, and the North Carolina Hospital Association, worked collaboratively to establish that practices are already in place for labs to assist patients and provide materials to patients when requested. These draft practices had earlier been provided to the Committee by Hugh Tilson. He noted these practices have been in place for some time.

Next the Committee heard remarks from Sam Taylor, President of the North Carolina Biosciences Organization (NCBIO). Mr. Taylor expressed concerns about possible unintended consequences of House Bill 795. He said the definition of pathological materials in House Bill 795 is extremely broad and applies to materials whether or not patient consent has already been obtained for the retention of the materials. As researchers, manufacturers, and clinical trial companies, they obtain consent to retain the materials and have concerns that the obtained consent should be binding. Investigators often compile large libraries of samples of individual tissue specimens and compare those samples to each other and other sample groups. This process allows researchers to learn about diseases and possible treatments for disease. The integrity of the research findings is dependent upon their ability to produce those samples and to reference them later. If samples are removed from the libraries, the value of those libraries and their findings is substantially impaired. As such, Mr. Taylor stressed that the bill could have an unintended impact on the areas of research, clinical trials, and manufacturing.

Bill Graham from the law firm of Wallace and Graham was the next speaker. He stated that several years ago, the ordinary way to obtain pathological materials was to present to the provider a medical release signed by the patient, advocate, or attorney. The tissue or specimen being requested would then be provided. Now, however, the risk/loss analysts for hospitals and pathologists are requiring a court order to obtain material. Mr. Graham expressed his opinion that it is time consuming, laborious, expensive and unnecessary to secure a court order. Mr. Graham expressed a desire to obtain pathological materials without a court order and stated that legislation should require that any material requested or investigated be returned to the lab at the end of any inquiry, investigation, case or otherwise.

The Committee then entered into a lengthy discussion about federal regulations and best practices for the retention of pathological materials. Staff was then directed to prepare a draft report based on the information and discussion from today's meeting, particularly focusing on the North Carolina Hospital Association's best practices and upon the guidelines from the College of American Pathologists. The Chair explained that the Committee will vote on the draft report at the January 4th meeting.

January 4, 2013

The Committee met on Friday, January 4, 2013, in Room 544 of the Legislative Office Building at 2:00 pm, at which time it discussed and voted to approve this final report to the 2013 General Assembly.

FINDINGS AND RECOMMENDATIONS

FINDINGS

The federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 contain regulations for the retention of pathological materials by clinical laboratories. Under 42 CFR 493.1105, a laboratory must retain for at least two years, the following materials:

- Test requisitions and authorizations.
- Test procedures.
- Analytic system records.
- Proficiency testing records.
- Laboratory quality systems assessment records.

Additionally a laboratory must retain cytology and histopathology slide preparations for at least five years from the date of examination. A laboratory must retain pathology specimen blocks for at least two years from date of examination.

In addition to the regulations found under CLIA, laboratories wishing to bill Medicare for patient services and to perform testing on human specimens must be CLIA certified or accredited. The College of American Pathologists (CAP) has been granted deemed status from the Centers for Medicare and Medicaid (CMS) to offer accreditation to laboratories under CLIA. The CAP regulations are more stringent than those found under CLIA for retention of pathological materials. For example, the CAP Retention of Laboratory Records and Materials requires fine needle aspiration slides and paraffin blocks to be retained for ten years.

The Committee heard testimony regarding requests made to pathologists for various pathological materials retained by the laboratories. There appear to be no concerns with requests made by physicians for purposes of research or medical treatment. However, there is concern about the need for a uniform procedure when the request is made by an attorney for large amounts of pathological materials. On one hand, the hospitals and laboratories must comply with federal retention laws and regulations. On the other hand, the attorney requires the information to best serve his or her client. Often the pathological material contains valuable information that is crucial to a patient's potential lawsuit. Laboratories need to ensure adherence to the law and regulations, while attorneys need to be able to access pathological material on behalf of their clients.

In light of the concerns surrounding requests for pathological materials, the North Carolina Hospital Association has expressed its member hospitals' commitment to providing access to laboratory materials while also protecting the accreditation and

licensures of the facilities. The Committee heard from the North Carolina Hospital Association regarding its work on developing Best Practice Principles ("Principles") with regards to requests for and release of pathological materials. A copy of the draft Principles presented to the Committee at its meeting on December 5, 2012, is enclosed at Appendix E.

The Principles are consistent with the 2003 Professional Relations Manual of the College of American Pathologists regarding records and materials requests. The Principles contain guidelines for materials requested for ongoing patient care, research requests, and requests from law firms and document retrieval firms, as well as address accreditation and regulatory compliance. With regards to concerns raised about the requirement of an attorney to obtain a court order, the Principles indicate that, unless the lab "has an objection based on other grounds, such as compliance with federal law, accreditation standards, evidentiary standards, or in order to protect medically necessary specimens for the patient's further diagnosis and treatment), no court order should be required for new slides," but that a court order or subpoena will be required to produce original slides and paraffin blocks.

The Committee finds that it is essential to strike a balance between maintaining appropriate adherence to federal regulations and best practices on the part of clinical laboratories and access to pathological materials by patients and their representatives. The North Carolina Hospital Association Best Practice Principles and the College of American Pathologists 2003 Professional Relations Manual appear to achieve this balance. Therefore the Committee offers the following recommendation:

RECOMMENDATION:

The Committee recommends that the General Assembly direct the Division of Health Service Regulation, Department of Health and Human Services (Department), and the North Carolina Medical Board (Board) to enact rules governing the procedures regarding the request for and release of pathological materials made to clinical laboratories within the jurisdiction of each respective entity. These rules must be consistent with the North Carolina Hospital Association Best Practices Principles and the College of American Pathologists 2003 Professional Relations Manual. The Department and the Board must develop these rules in consultation with one another to ensure consistency in procedures governing pathological materials.

Appendix A

COMMITTEE MEMBERSHIP

2011-2012

President Pro Tempore of the Senate Appointments:

Senator Thom Goolsby, Co-Chair

Senator Peter Brunstetter
Senator Andrew Brock
Senator Louis Pate
Senator William Purcell

Speaker of the House of Representatives Appointments:

Representative Tom Murry, Co-Chair

Representative William Brisson
Representative Bert Jones
Representative Chuck McGrady
Representative Sarah Stevens

Appendix B

COMMITTEE CHARGE

Pathological Materials – The LRC Study Committee on Pathological Materials shall study the issue of access by patients to pathological materials requested by a patient for the purpose of additional medical treatment evaluation or the evaluation of any legal rights of the patient. Specifically, the Committee shall consider:

1. State and federal laws and regulations that govern the administration, operation and certification of pathology laboratories;
2. State and federal laws that govern the maintenance and production of a patient's medical records;
3. Appropriate changes in state law that ensure patient access to pathological materials that are needed to obtain and evaluate the patient's medical needs and legal rights while also balancing pathology laboratories' duties to comply with federal and state licensure laws and regulations, patient care responsibilities, risk management obligations, and other relevant issues;
4. The impact of any state law change on the medical research industry including: pharmaceutical companies; government research institutions; and other industries dependent upon information obtained from pathological materials.

While conducting this study the Committee shall consult:

1. Persons who serve as advocates for patients who have requested pathological materials;
2. Patients who have requested pathological materials from health care providers;
3. Representatives of hospitals responsible for the management of pathology laboratories;
4. Pathologists responsible for the management of pathology laboratories;
5. Persons responsible for providing legal advice to mangers of pathology laboratories; and
6. Any other person or persons the Committee deems appropriate.

Senate Members		**House Members**	
Sen. Goolsby	Chair	Rep. Murray	Chair
Sen. Brunstetter	Member	Rep. Brisson	Member
Sen. Brock	Member	Rep. Jones	Member
Sen. Pate	Member	Rep. McGrady	Member
Sen. Purcell	Member	Rep. Stevens	Member

STATUTORY AUTHORITY

NORTH CAROLINA GENERAL STATUTES
ARTICLE 6B.

Legislative Research Commission.

§ 120-30.17. Powers and duties.

The Legislative Research Commission has the following powers and duties:

(1) Pursuant to the direction of the General Assembly or either house thereof, or of the chairmen, to make or cause to be made such studies of and investigations into governmental agencies and institutions and matters of public policy as will aid the General Assembly in performing its duties in the most efficient and effective manner.

(2) To report to the General Assembly the results of the studies made. The reports may be accompanied by the recommendations of the Commission and bills suggested to effectuate the recommendations.

(3), (4) Repealed by Session Laws 1969, c. 1184, s. 8.

(5), (6) Repealed by Session Laws 1981, c. 688, s. 2.

(7) To obtain information and data from all State officers, agents, agencies and departments, while in discharge of its duty, pursuant to the provisions of G.S. 120-19 as if it were a committee of the General Assembly.

(8) To call witnesses and compel testimony relevant to any matter properly before the Commission or any of its committees. The provisions of G.S. 120-19.1 through G.S. 120-19.4 shall apply to the proceedings of the Commission and its committees as if each were a joint committee of the General Assembly. In addition to the other signatures required for the issuance of a subpoena under this subsection, the subpoena shall also be signed by the members of the Commission or of its committee who vote for the issuance of the subpoena.

(9) For studies authorized to be made by the Legislative Research Commission, to request another State agency, board, commission or committee to conduct the study if the Legislative Research Commission determines that the other body is a more appropriate vehicle with which to conduct the study. If the other body agrees, and no legislation specifically provides otherwise, that body shall conduct the study as if the original authorization had assigned the study to that body and shall report to the General Assembly at the same time other studies to be conducted by the Legislative Research Commission are to be reported. The other agency shall conduct the transferred study within the funds already assigned to it.

Appendix D

LEGISLATIVE PROPOSALS

Appendix D

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013

U **D**

BILL DRAFT 2013-TKz-1 [v.3] (12/10)

(THIS IS A DRAFT AND IS NOT READY FOR INTRODUCTION)
12/10/2012 4:21:18 PM

Short Title:	Develop Rules for Release of Path Materials.	(Public)
Sponsors:	(Primary Sponsor).	
Referred to:		

A BILL TO BE ENTITLED

AN ACT DIRECTING THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE NORTH CAROLINA MEDICAL BOARD TO DEVELOP RULES GOVERNING REQUESTS FOR AND RELEASE OF PATHOLOGICAL MATERIALS AS RECOMMENDED BY THE LEGISLATIVE RESEARCH COMMISSION ON PATHOLOGICAL MATERIALS.

The General Assembly of North Carolina enacts:

SECTION 1. The Division of Health Service Regulation, Department of Health and Human Services (Department) shall enact rules governing the procedures regarding the request for and release of pathological materials made to clinical laboratories within the jurisdiction of the Department. These rules shall be consistent with the North Carolina Hospital Association Best Practices Principles and the College of American Pathologists 2003 Professional Relations Manual and shall be developed in consultation with the North Carolina Medical Board to ensure consistency in procedures governing pathological materials.

SECTION 2. The North Carolina Medical Board (Board) shall enact rules governing the procedures regarding the request for pathological materials made to clinical laboratories within the jurisdiction of the Board. These rules shall be consistent with the North Carolina Hospital Association Best Practices Principles and the College of American Pathologists 2003 Professional Relations Manual and shall be developed in consultation with the Division of Health Service Regulation, Department of Health and Human Services to ensure consistency in procedures governing pathological materials.

SECTION 3. This act is effective when it becomes law.

SUPPORTING MATERIALS

Appendix E

NC Hospital Association Best Practices Principles

From: Hugh Tilson, Senior Vice President, NC Hospital Association

December 4, 2012 – FINAL DRAFT

PRINCIPLES:

Hospitals and labs in North Carolina will ensure that the procedures to request patients' pathological materials comply with the following general principles.

Hospitals and labs that cannot comply with the following principles for any request, in order to ensure that patient specimens are retained for compliance with federal law, accreditation standards, evidentiary standards, or in order to protect medically necessary specimens for the patient's further diagnosis and treatment, shall provide the reason(s) for not complying to the requestor.

A. MATERIALS FOR ONGOING PATIENT CARE

To meet ongoing patient care and accreditation/regulatory compliance requirements, original slides and blocks remain in [LAB/SYSTEM NAME] files as part of the patient's permanent medical record.

A copy of [LAB/SYSTEM NAME] report will be sent to the patient or another medical institution caring for the patient upon request.

Recut sections and unstained slides when requested will be sent to other medical institutions or physicians for continued patient care or for consultation upon request unless inadequate supply of sample exists or if recutting would damage the sample. The original sample or block shall not be forwarded, unless deemed appropriate by the [LAB/SYSTEM NAME].

B. RESEARCH REQUESTS:

For researchers not within [LAB/SYSTEM NAME], the researchers must document IRB approval at their institution. Once that is received, a [LAB/SYSTEM NAME] pathologist will ascertain what materials are present in [LAB/SYSTEM NAME] files and which may be recut for research purposes. No blocks will be forwarded from [LAB/SYSTEM NAME] for research purposes, unless deemed appropriate by [LAB/SYSTEM NAME]. If sufficient tissue is present, the outside researcher will be offered recut or unstained sections.

For researchers within [LAB/SYSTEM NAME], the request must be reviewed by a designated pathologist or the pathologist who signed the case out who will determine whether sufficient tissue is present to recut the blocks.

DECEMBER 4, 2012 DRAFT PRINCIPLES

C. REQUESTS FROM LAW FIRMS AND DOCUMENT RETRIEVAL FIRMS:

An appropriate authorization for release of medical records and unstained or new prepared hematoxylin and eosin (H&E) stained slides must accompany the request and must meet the following criteria (including, but not limited to)

- Signed within the last year
- Signed by the patient, a legal guardian or the executer of the patient's estate

In addition, a written signed request must be submitted by a law firm, together with information about reimbursement of cost for the slides. Unless the [LAB/SYSTEM NAME] has an objection on other grounds (including compliance with federal law, accreditation standards, evidentiary standards, or in order to protect medically necessary specimens for the patient's further diagnosis and treatment), no court order should be required for new slides.

In any case, the laboratories should make available to the attorney's expert witness a place in the laboratory where the original slides (and blocks if that matters) can be examined at a mutually agreeable time, which obviates harm to the integrity of the patient's medical record or specimen retention requirements. Digital scanning of slides at levels equivalent to the original slides themselves is a technology becoming available, which also obviates any damage to the tissues. The foregoing authorizations are required in these cases as well.

D. ACCREDITATION/REGULATORY COMPLIANCE

Recut sections will be provided when available.

To ensure compliance with federal law, accreditation standards, evidentiary standards, or in order to protect medically necessary specimens for the patient's further diagnosis and treatment, original slides and/or paraffin blocks will be provided only upon receipt of a Court Order or subpoena from a court with appropriate jurisdiction.

Reasonable fees may be charged for the provision of documents, recut sections or other materials provided.