Volume 13 Number 1 Spring / Summer 2000

AT RISK

ASHRM
NORTH CAROLINA CHAPTER
A risk management publication written by the members of the North Carolina Chapter of the American Society for Healthcare Risk Management

President's Letter

Welcome to the new millenium! I hope this newsletter finds each of you well and with renewed ambition for the challenges of the upcoming year!

As you may know, the torch of leadership has been passed to several key positions within our organization. Those changes are listed in this newsletter. Special thanks goes out to those who have completed their service on the board or through committee work.

I hope you were able to attend the Southeastern Regional Conference held in Charlotte on May 17-19. Guests included members from the ASHRM Chapters of Georgia, South Carolina, Tennessee and Alabama. Special thanks to Vickie Haddock for chairing the steering committee for this conference.

The board met in February to discuss the budget for the upcoming year. The majority of the board meeting was dedicated to short and long range planning for the chapter.

As some of you may know, this year marks North Carolina ASHRM's 20-year anniversary. Through the years, many have come and gone, but a select few have been here since "the earth cooled." This year we'll recognize our past members and achievements along with congratulating those who have served so faithfully. We are planning a special celebration for the fall meeting and would like to display any artifacts from those pioneer days. If you are in possession of any historic information (documents, correspondence, ect.), please forward originals or copies to me. I will work with the chapter historian on preparing a display for our fall meeting.

Doug Borg has constantly been adding information to our website. Thanks to Doug for taking time to maintain this for us. The internet is constantly evolving and will continue to grow as a means of communication. Check us out at nc-ashrm.org.

Continued on page 6

OIG: Watch For Individuals Excluded From Medicare

Everyone knows that the really big penalty for Medicare and Medicaid fraud is the hospital's exclusion from participation in those and other federal programs, but the government is reminding risk managers that individuals can be excluded also. And if they are, they should not be welcome at your facility, according to a federal advisory.

The U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) recently issued an advisory to health care providers suggesting they should determine whether potential and current employees and contractors have been excluded from participation in federal health care programs, including Medicare and Medicaid.

The advisory explains that an effect of an OIG exclusion from federal health care programs is that no federal health care program payments may be made for any items or services furnished, directly or indirectly, by an excluded individual or entity. Almost 17,000 individuals and entities have been excluded from participating in federal health care programs for misconduct including fraud convictions, patient abuse, and defaulting on health education loans. In fiscal year 1999, the OIG expects to exclude about 3,000 individuals and entities.

"Exclusion is one of the most important tools we have to protect beneficiaries and stem fraud and abuse in federal health care programs," Inspector General June Gibbs Brown said in the advisory. "To

Continued on page 7

Republished with Permission from ASHRM
The following was a Member Alert released on
Tuesday, March 21, 2000

FOOD AND DRUG ADMINISTRATION PROPOSED STRATEGY ON REUSE OF SINGLE-USE MEDICAL DEVICES

BACKGROUND

Last November, the FDA released a proposed strategy for addressing the practice of reuse of medical devices that are intended to be used only once. The proposed strategy is designed to "protect the public health by assuring that the practice of reprocessing and reusing 'single-use' products is based on good science."

Under the proposed strategy, the FDAwould consider regulating third-party processors and health care facilities that engage in reprocessing of single-use devices the same way the agency has regulated OEMs (Original Equipment Manufacturers). This includes: registration and listing of firms, premarket notification and approval requirements, submission of adverse event reports under the Medical Device Reporting regulation, manufacturing requirements under the Quality Systems regulation, labeling requirements, medical device tracking, and medical device corrections and removals.

Also, the FDAbelieves that the regulatory controls over reprocessed single-use devices should be commensurate with the risk they pose to patients. The FDA sought input on the development of a device categorization system. Public meetings were held in December to collect feedback from interested parties.

The FDAis also considering whether OEMs should provide information on the label of their single-use products to alert users and reprocessors of the risks and vulnerabilities associated with reprocessing of their specific single-use devices.

In response to concerns presented by various interest groups, the FDA has developed the following two companion draft guidances that would implement the proposed enforcement strategy: (1) "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," and (2) "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (RPS). These documents are available at:
http://www.fda.gov/cdrh/reuse/1029.pdf and http://www.fda.gov/cdrh/reuse/1156.pdf respectively and are summarized as follows:

ENFORCEMENT PRIORITIES

The document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" covers the FDA proposed strategy on enforcing current *manufacturer* regulations on hospitals and other third party firms that reprocess single-use medical devices. According to the FDA, anyone who reprocesses a single-use device is a manufacturer. As such, the following requirements may apply:

- Device registration and listing
- Good manufacturing practice (GMP) inspection
- Medical device reporting, tracking
- General labeling requirements
- Pre-market submissions (510(k) and pre-market approval)

Understanding that it would cause a great deal of trouble and expense to hospitals to comply with the above requirements, the FDAhas proposed that devices be separated into different categories based upon their risk and will phase in enforcement based upon the classification of the device. This is called the Review Prioritization Scheme (RPS). The RPS is discussed in detail in the "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" document which will be summarized later.

Under the proposed strategy, there are three device categories: (1) high-risk; (2) moderate risk; and (3) low risk. The enforcement discretion ***phase-in*** strategy for hospitals is summarized in the chart below:

	Pre-Market Requirements	All Other Requirements
High Risk	1 year	6 months
Moderate Risk	18 months	6 months
Low Risk	2 years	6 months

*All time periods begin on the date of the issuance of the final reuse of single use device enforcement guideline.

The enforcement document outlines in detail the specifics of all reporting requirements including what is expected of hospitals and third party reprocessors.

REVIEW PRIORITIZATION SCHEME (RPS)

The document entitled ìReprocessing and Reuse of Single-Use Devices: Review Prioritization Schemeî supplements the enforcement document by outlining the criteria that the FDAwill utilize in determining whether a device is high, moderate or low risk. It includes a decision-making flowchart to facilitate classification of devices. Devices are evaluated for two types of risks: (1) risk of infection and (2) risk of inadequate performance after reprocessing.

In evaluating infection risk, the FDAis taking into consideration the following:

- If the device is non-critical
- Post-market information that is currently available
- Features of the device that may prevent appropriate cleaning
- Similar reusable devices
- Consensus standards, if applicable.

In evaluating the risk of inadequate performance after reprocessing, the FDA is taking into consideration the following:

- Post market information that is currently available
- The potential outcome if a device fails (i.e., serious injury or death)
- The materials used in making the device
- Consensus standards, if applicable
- The ability to visually identify flaws caused by reprocessing.

The RPS document provides a breakdown of each factor in determining risk, as well as providing samples to guide the reader through the process. It should be noted that all implantables are automatically considered high risk under the RPS.

ISSUES EXPERTS HAVE IDENTIFIED FOR CONSIDERATION

- Hospitals being required to submit pre-market data just as manufacturers do;
- Hospital reprocessing often done under physician supervision in settings already under watch by JCAHO, the Health Care Financing Administration, state licensing authorities, and hospitals themselves;
- The proposed FDApolicy not applying to physician offices and ambulatory surgical centers, which are projected to be dominant settings for surgeries within five years;
- Suggested exemption from the policy devices that are taken from packages but unused;
- Making manufacturers back up *single use* labels with evidence that re-use is unsafe;
- Development of consensus standards, including *best practices* for low-risk devices; and
- Directing research on reuse at complex, high-risk devices.

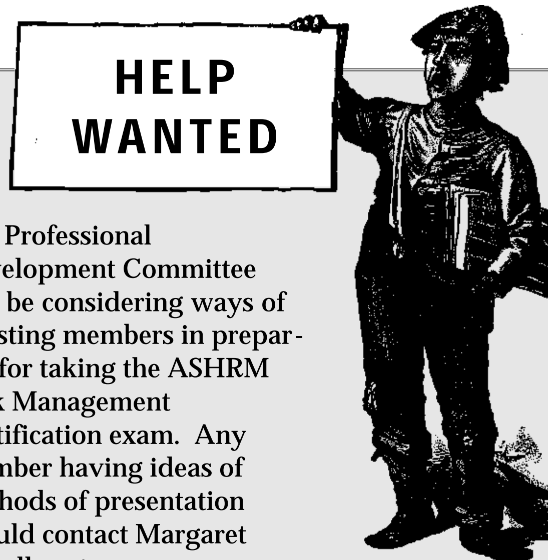
The FDAhopes by summer to complete a policy on re-use of *single use* devices, and have ensuing regulations take effect within about a year.

ADDITIONAL RESOURCES

For further information on this subject, please see the following web site resources:

- American Hospital Association's web site at www.aha.org, "Advocacy and Representation," 2000 Annual Meeting Advocacy Materials.
- Association for Professionals in Infection Control and Epidemiology, Inc.'s web site at www.apic.org, "Government Affairs."
- The Association of periOperative Registered Nurses' web site at www.aorn.org, "Clinical Practice," "Top 10 Clinical Questions," "Reprocessing Single Use Items."

This Member Alert is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that ASHRM is not engaged in rendering legal, accounting, or other professional service. If legal advice or other expert assistance is required, the services of a competent professional should be sought.



The Professional Development Committee will be considering ways of assisting members in preparing for taking the ASHRM Risk Management Certification exam. Any member having ideas of methods of presentation should contact Margaret Broadhurst (mbroadhurst@dgh.org) or (910) 296-2696.

The Public Relations/Marketing Committee needs assistance from the Chapter members to contribute articles for inclusion into future newsletters. If you have written an article, or have information that may be beneficial to the chapter members please forward your articles to Tom Green (greent@mcneary.com) or fax to (704) 365-7114.

Do you have editorial experience or know someone who does? We are in need of filling the newsletter editor position that was recently vacated by Carol Hardman. If you might be interested please contact Tom Green (greent@mcneary.com) or (704) 365-4150.

Meet Our New Members

Teresa (Teri) Gutierrez
Marsh Advantage America

Married with 3 children, Teri has spent the past 5 years with Marsh and currently manages their Raleigh office. She has traveled to Germany with her husband several times serving as a singer and bell ringer for a German Omph Band.

Amy Hill
Assistant Risk Management Specialist
Medical Mutual Insurance Company

Agraduate from UNC Chapel Hill, Amy is new to the healthcare field and is involved in the planning and development of Risk Management seminars for Medical Mutual. An active runner and triathlete, she enjoys mountain biking, whitewater rafting, kayaking and hiking.

Deana Allen, RN,MBA,ARM
Senior Healthcare Risk Consultant
Zurich U.S. Healthcare

Deana began her career in healthcare in the early 80's and has served as Director of Corporate Risk Services for a large integrated healthcare system in Atlanta. Deana joined Zurich in 1998 as a Healthcare Risk Consultant for the Southeast Region.

Mark Alan Hudson, FACHE
VP- Administrative Services
Cleveland Regional Medical Center

Born and raised in the Tidewater Area of Virginia where he attended the University of Virginia, Mark spent 5 years at the University of VAHospitals before pursing his MHAat the Medical College of Virginia. He has been with Cleveland Regional Medical Center since 1883 holding a number of positions before assuming the role of VPñ Administrative Services. Mark is also a freelance writer with almost 500 articles to his credit which have appeared in more than two dozen publications including the ASHRM journal!

Martha T. Efstation,RN,BSN
Risk Analyst
Mission-St Josephís Hospital

Martha has spent the past 10 years with Mission/St Josephís Hospital serving the past two years in risk management and 6 years in Quality Improvement. She is married with three children and enjoys hiking, art, and reading.

Sandra Clayton
Claim Consultant
MMI Companies

Anative of Durham, Sandra began her career in the insurance industry in 1978 with State Farm Insurance Company. From 1984 to 1992 she worked for Reliance Insurance Company and in 1992 she joined Century American Insurance Company as a claims consultant in Medical Professional Liability. In 1999 Sandra joined MMI. She is married and enjoys auctions, crafts, fall festivals and spending time with her mother.

Robin Garner
Vice President and Client Executive
Marsh USA Inc.

Robin has worked in the insurance industry for 15 years, the last 10 years with Marsh working with hospitals in South Carolina.

Lajuanda Johnson
Underwriter
The Healthcare Group at Zurich U.S.

Lajuanda is a healthcare underwriter for North Carolina and Tennessee. Prior to joining Zurich, she worked for Marsh USA and AIG as an underwriter for healthcare liability. She is the proud mother of two sons and resides in Stone Mountain, Georgia.

Marian Sigmon
Assistant Vice President of Administration
Watauga Medical Center

Agraduate of Appalachian State University, Marian is married with a beautiful daughter named Chelsea. He has spent 10 years in pre-hospital care as the Assistant Director of the County Ambulance Service and the past 10 years at Watauga Medical Center.

Keri Otto
Risk Management Coordinator
Dorothea Dix Hospital

Keri became the first to obtain the title of Risk Manager at Dorothea Dix Hospital in April of 1999. Her background is in speech pathology and long-term care. Married with 3 dogs, she obtained her B.S. from Purdue University and received an MA from Ball State University.

Past President's Letter

1999 was a great year for the North Carolina Chapter. The Fall meeting held at Graylyn Conference Centers in Winston-Salem was especially nice. It is the former home of Bowman Gray. The home is magnificent and full of history. Bowman Gray, Jr., donated it to Wake Forest for use as a conference center. We had a grand time, with the Murder Mystery, and the socials. If you were not there, you were missed.

Our meetings were well attended with approximately 100 members at each meeting. We have provided 17 hours (3 days) of education to our members at our Spring and Fall meetings, co-sponsored 2 education programs with chapter sponsors and co-sponsored Module I with Virginia ASHRM. Module I was attended by 29 members of NC and VA ASHRM. We all wish the members who have started down the "module path" success. Next year we look forward to joining with the Chapters from Georgia, Tennessee, South Carolina and Alabama to provide a "regional" meeting to members from these Southeast Chapters. We expect to have "national" speakers on a variety of timely topics.

This program is the Second South East Regional meeting and is scheduled May 18-20 in Charlotte, NC. The First was held in May of 1996 and was such a success, we thought we would do it again. We are looking at a workshop for experienced Risk Managers planning to sit for the first CPHRM examination in June. It will likely be set up as a group study. Margaret Broadhurst will be mobilizing the NC ASHRM Professional Development Committee on this project.

New Officers and Board Members assumed their office on January 1, 2000. They are:
Chuck Mantooth, President
Richard Thompson, Vice President
Barbara Hendrix, Secretary
Sheila Elliott, Member at Large

Continuing on the Board are:
Sharon Musselman, Treasurer
Cynthia De Fusco, Past President
Tom Green, Member at Large
Michelle Temple, Member at Large
Margaret Broadhurst, Member at Large
Jean Rhodes, Member at Large

Our Fall meeting in 2000 will be held in Sunset Beach, NC. This is a new location for us and may offer an opportunity for a Golf Tournament. Look for details in the coming months. Chuck is setting us on a path to more great educational and social events.

I have greatly enjoyed my year as your President. I am grateful for the confidence you placed in me and the honor you granted. It will always be my greatest professional achievement. I look forward to continuing to work with and support this chapter. My respect and admiration for each of you grows daily. Thank you, again.

Cynthia DeFusco
Past President

At our 1999 Fall Meeting, Margaret Broadhurst, Chair of the Professional Development Committee, presented the Professional Development Recognition Awards to the following individuals:

Nan Holland received the Workhorse Award for her outstanding contributions and time devoted to the Chapter.

Bobbie Hendrix received the Workhorse Award and Professional Recognition Award for her continued dedicated support to the Chapter and educational achievements. It was also noted that Bobbie was awarded the Fellow designation by ASRHM at the annual business meeting in Chicago earlier in the Fall.

PERSONAL AUTO AT WORK

Your employee comes screaming into your office "What do you mean you won't cover my auto accident? I was going to the bank for the company when I hit that crazy school bus driver?"

An employee who uses a personal auto at work often mistakenly believes that the employer's auto insurance policy will cover the personal auto while used on company business.

Actually, the employee, whether on company business or personal pleasure, is responsible for their own auto insurance protection. This includes both liability and physical damage coverages.

No corporate insurance program, without modification, will cover the employee's liability under the corporations Business Auto policy. The same is true of physical damage coverage on employee's autos, which is rarely seen and which is not addressed by this article.

An employer's Business auto policy may not respond on behalf of an employee using their personal auto on company business.

A properly written Business Auto insurance policy should cover the corporation for any automobile, whether owned, hired, borrowed, or rented.

While an employee has no protection through the corporate policy, the corporation (properly insured) is covered for all incidents arising out of the employee's use of any auto while on company business.

If an employee has an accident in a personally owned vehicle while on official business for the company, the employee's personal policy would first pay damages on behalf of the employee. Then the personal policy would pay on behalf of the company. However, the company's policy (if not properly endorsed) would not respond on behalf of the employee.

You are urged to repeatedly inform all employees how Business Auto Liability coverage works. The company should also explain that a portion of the employee's mileage reimbursement contemplates the purchase of adequate personal liability insurance at suggested minimum limits of $300,000, physical damage coverage on their auto as they believe appropriate and any physical damage deductibles they may incur.

As a benefit to your employees, you may wish to modify your commercial auto policy to provide them coverage excess of their own personal auto policy, when they are using their vehicle on company business. The cost is nominal.

We recommend that you have a written company Policy Statement outlining the items mentioned above that apply to your organization.

Continued from page 1

Lastly, national ASHRM has had it's ***ears to the ground.*** NC ASHRM and other state chapters have voiced concerns about the amount of effort being put into chapter achievement versus the benefits. As you may know, chapter achievement has been the backbone of outlining steps for chapters to be successful. Many chapters (including NC ASHRM) feel that the process has lost its focus and that more attention is being directed towards obtaining points rather than meeting the needs of the membership. For this reason, national has decided to form a president's council to make changes to the chapter achievement process. These changes will impact the work that is currently being done by our committees and our organization as a whole. I will keep you updated as these changes unfold.

It is an honor to work with such an outstanding board and membership. I look forward to serving you in the year 2000!

— Chuck Mantooth

Continued from page 1

ensure that Medicare, Medicaid and other federal health care programs are protected, we need the cooperation of the entire health care community to help make sure excluded individuals are not involved in any way in the care of federal program beneficiaries."

VIRTUALLY ALL FEDERAL PROGRAMS AFFECTED

Both the Health Insurance Portability and Accountability Act of 1996 and the Balanced Budget Act of 1997 expanded and strengthened the OIG's exclusion authorities. One of the most significant changes has been the expansion of the OIG's exclusion authority beyond HHS programs, such as Medicare and Medicaid, to all federal health care programs, including those administered by the Department of Veterans Affairs and the Department of Defense. The only federal health care program not covered by the OIG's exclusion authority is the Federal Employees Health Benefits Program.

The OIG also has the authority to impose civil monetary penalties against excluded individuals and entities that seek reimbursement from federal health care programs, as well as health care providers that employ or enter into contracts with excluded individuals to provide items or services to federal program beneficiaries. In both cases, civil monetary penalties of $10,000 for each item or service furnished by the excluded individual may be imposed, and the responsible party may have to pay three times the amount claimed for each item or service.

"The prohibition against federal program payment for items or services furnished by excluded individuals and entities extends to payment for administrative and management services not directly related to patient care," the advisory says. "In short, no federal program payment may be made to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care. The payment prohibition applies whether federal payment results from itemized claims, cost reports, fee schedules or a prospective-payment system."

"In short, no federal program payment may be made to cover an excluded individual's salary, expenses, or fringe benefits ... "

— OIG advisory

Health care providers that receive federal health care funding may employ an excluded individual only in limited situations where the provider is able to pay the individual exclusively with nonfederal funding and the items and services furnished by the excluded individual relate solely to nonfederal program patients.

Here are some examples in the advisory bulletin of situations that can expose excluded parties and their employers to civil money penalties:

- services performed by excluded nurses, technicians, or other excluded individuals who work for a hospital, nursing home, home health agency, or physician practice, where such services are related to administrative duties, preparation of surgical trays, or treatment plan reviews if such services are reimbursed, directly or indirectly, by a federal health care program, even if the individuals do not furnish direct care to federal program beneficiaries;
- services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs reimbursed, directly or indirectly, by a federal health care program;
- administrative services, including the processing of claims for payment, performed by an excluded individual for a Medicare fiscal intermediary or carrier or a Medicaid fiscal agent;
- services performed for program beneficiaries by excluded individuals who sell, deliver, or refill orders for medical devices or equipment reimbursed, directly or indirectly, by a federal health care program;
- items or equipment sold by an excluded manufacturer or supplier used to care for or treat a federal program beneficiary and reimbursed, directly or indirectly, by a federal health care program.

CHECK THE WEB

The OIG maintains a list of excluded individuals and entities accessible on the World Wide Web at www.hhs.gov/oig/cumsan/index.htm and urges health care providers to check the list before hiring or contracting with individuals or entities. Additionally, the OIG recommends that health care providers periodically check the list to determine the exclusion status of current employees and contractors. The OIG also will provide advisory opinions on specific employment or contractual arrangements that may violate the law.

Reprinted from February 2000 /HEALTHCARE RISK MANAGEMENT'"

TIMELINE OF EVENTS FOR 2000-2001

Date	Location	Event
April 30-May 5, 2000	**San Francisco, CA**	**RIMS Conference**
May 18-20, 2000	**Charlotte, NC**	**SE Regional Conference**
October 4-6, 2000	**Sunset Beach**	**NC ASHRM Fall Conference**
November 2-5, 2000	**New Orleans, LA**	**ASHRM Anjual Conference**
April 29-May 4, 2001	**Atlanta, GA**	**RIMS Conference**
October 28-31, 2001	**Boston, MA**	**ASHRM Annual Conference**
April 14-19, 2002	**New Orleans, LA**	**RIMS Conference**

WWW.NC–ASHRM.ORG

ASHRM
NORTH CAROLINA CHAPTER
P.O. Box 72248
Durham, NC 27722-2248

NC ASHRM BOARD 2000

Name/Mailing Address	NC ASHRM Title	Email	Work Phone	Work Fax	Home Phone
Borg, Rina NC ASHRM PO Box 72248 Durham, NC 27722-2248	Executive Assist.	Borg01@ACPUB.Duke.EDU	919-479-2098	919-471-9231	919-479-2098
Broadhurst, Margaret Director, QA/RM Duplin General Hospital 401 North Main Street Kenansville, NC 28349-0278	Board Member Profess. Dev. Comm	Mbroadhurst@aol.com	910-296-2696	919-296-1174	910-630-2329
DeFusco, Cynthia Onslow Memorial Hospital PO Box 1358 Jacksonville, NC 28541-1358	Past President Nominating Comm.	cdefusco_omh@coastalnet.com	910-577-2517	910-577-2881 cell 252-240-9962	252-354-6366
Elliott, Sheila Claim Analyst CaroniaCorp PO Box 147 Redsville, NC 27328	Board Member Legislative Comm.	sheila.elliott@cna.com	336-634-0220	336-634-0215	336-342-5332
Green, Tom McNeary Healthcare Ser. PO Box 220926 6525 Morrison Blvd Charlotte, NC 28222	Board Member PR/Marketing Comm.	greent@mcneary.com	800-729-4149	704-365-7114 cell 704-408-1016	704-947-9452
Hendrix, Bobbie Dir, DUHS Coin Risk Mgmt Box 3811 DUMC Durham, NC 27705	Secretary	Hendr001@mc.duke,edu	919-684-3277	919-681-8618 cell 919-218-5121	919-383-4911
Mantooth, Charles F. (Chuck) Account Executive McNeary Haealthcare Services PO Box 220926 6525 Morrison Blvd Charlotte, NC 28222	President	mantoothc@mcneary.com	800-729-4149	704-365-7114	704-862-0016
Musselman, Sharon Medical Protective 2000 Regency Pk, Ste 295 Cary, NC 27511	Treasurer	smusselman@medprotect.com	919-467-8370	919-380-1775	919-542-6251
Rhodes, Jean Coord, Quality Assurance Valdese General Hospital Valdese, NC 28690	Board Member Chapater Achievement	jmrhodes@vgh.org	828-879-7548	828-437-3959	
Temple, Michelle Dir, Risk Management Wake Medical Center 3000 New Bern Avenue Raleigh, NC 27610	Board Member Membership Comm	mtemple@wakemed.org	919-250-8234	919-250-8868	919-783-5344
Thompson, Richard Dir, Risk Management Albemarle Hospital PO Box 1587 Elizabeth City, NC 27102	Vice President Program Committee	rthompson@albemariehop.org	252-331-4651	252-331-4381	