Risk Rx

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STATE UNIVERSITY SYSTEM of FLORIDA
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SELF-INSURANCE PROGRAMS

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Small-Scale Grant Awards Programs:

Professional Liability Insurance Partnerships with Providers Aim to Reduce Claims and Improve Patient Safety

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In growing numbers, medical professional liability (MPL) insurers are tapping into a wealth of expertise, innovation, and energy by awarding small grants to fund patient safety, claims reduction, and loss prevention initiatives that are developed by the healthcare providers they insure, with promising results.

The W. Martin Smith Award Program, established by the University of Florida's Academic Medical Center Self-Insurance Program (SIP) and Continuing Medical Education office (CME), is a well-recognized example of just how much a small amount of funding, for projects designed by insured providers, can accomplish in improving patient safety and reducing the potential for claims and lawsuits.

Award program background and philosophy

The University of Florida Self-Insurance Program is the professional liability entity for the six colleges of the University of Florida Health Science Center and the health-related colleges at Florida State University, University of Central Florida, Florida International University, and Florida Atlantic University. In the latter part of 2011, SIP collaborated with the University of Florida's Office of Continuing Medical Education (UF CME) to expand upon the existing UF CME clinical quality award program to form the W. Martin Smith Interdisciplinary Patient Quality and Safety Award Program (IPQSA). Intrinsic to the Smith program philosophy is that by financing provider resourced projects, the passion, vitality, and expertise of these healthcare professionals working directly in their local area of interest will have a high probability of directly advancing patient safety, reducing claims, providing a substantial impact in the short term, and then becoming self-sustaining in the long term. By providing resources to several small, focused projects that complement claims reduction and patient safety objectives, as opposed to investing in large, long-term, multi-initiative projects, the program is seeing multiple simultaneous improvements over a short period.

Award framework

The Smith Awards are presented twice annually and do not exceed $25,000. The Smith Award selection process has been very competitive, with approximately three applications submitted for every grant awarded.

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Successful award applicants typically take a multi-disciplinary approach to their projects, and they have a strong implementation plan that includes a sound methodology for evaluating their project's impact and sustainability. To help ensure early compliance with award criteria, a "letter of interest" is required 30 days in advance of the project application due date. Following review of each letter of interest, feedback is provided to the applicant. An interdisciplinary selection committee, comprised of physicians, quality officers, patient safety and risk management professionals, nurses, administrators, and medical-legal attorneys, then reviews the accepted award applications against established criteria, to ensure objectivity in the selection process. If an applicant's project is selected for a Smith Award, the project's principal investigator executes a grant agreement that specifies award criteria and grantee responsibilities, including the submission of quarterly progress reports and a brief mid-point presentation that is made to award administrators and the next cycle of awardees. Smith Award recipients are required to complete their projects within 18 months. Projects must be approved by the University of Florida Institutional Review Board (IRB) prior to the release of award funds. Strict budget parameters prevent the use of award funds for offseting what would more appropriately be categorized as a capital budget expense item, such as clinical equipment. Upon completion of their projects, award recipients must also create a CME approved program, a peer-review publication, or some other scholarly activity.

Table 1 Projects Funded

Project Title	Award Amount
Improving Patient and Family Centered Care: A Family Partner for the Inpatient Unit at Shands Hospital for Children at the University of Florida	$23,050
Developing a Second Victim Staff Pilot Program for the Consequences of Unanticipated Clinical Events	$24,381
Implementation of a Hospital Based Discharge Intervention to Improve Heart Failure Readmissions	$24,540
Implementation of a Prospective Quality Assessment Program for the UF-Shands Breast Cancer Program	$27,318
Prehospital Sepsis Recognition	$24,974
Venous Air Embolism (VAE): A Widespread and Likely Fatal Complication and the Development of a Multidisciplinary Simulation Model for the Education of the Physiology, Detection and Management of VAE	$25,000
Management of the Traumatic Brain Injury Patient in Acute Care	$15,000
Impact of Structured Support Group on Quality of Life & Disease Course in Teenagers with Inflammatory Bowel Disease	$11,069
Implementation of a Protocol, for Early Identification & Management of Sepsis, Severe Sepsis/Septic Shock Patients—An Institution Wide Multidisciplinary Collaborative	$25,000
Improving Physician/Patient Communication with AIDET (Acknowledge, Introduce, Duration, Explanation Thanks)	$5,131
Medication Error by Hospitalized Patients and Analysis of Patient Satisfaction Using a Daily Medication List	$10,700
Best Fed Beginnings: A First Step	$15,000
The Effect of a Pain Management Protocol on Postoperative Neurosurgical Pain	$24,200
Impact of Collaborative Care Services for High-Risk Patients after Discharge from a Large Urban Academic Medical Center	$11,113
Building Infrastructure to Develop and Promote a Culture of Safety: A Pilot Program for General Surgery Patients	$24, 975
Pressure Ulcers: Crisis of Prevention	$24,100
Implementation of Obstetric Emergency Simulation Drills	$20,000
Communication Intervention to Improve Patient Experience during a Genetic Counseling Visit: Pre-Visit Pilot Project	$18,900

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Award program participation

Since the initial Smith Awards, in January 2012, the partnership between the UF CME office and SIP has resulted in more than $441,750 awarded to fund 27 grants that address a wide variety of improvement initiatives (Table 1). Because a large percentage of the Smith Award projects are still currently within their 18-month cycle of implementation, impact analyses and claims reduction efforts are of necessity pending on many projects. However, several funded projects are yielding very promising results. One award was given to Dr. Linda Le-Wendling, MD, Assistant Professor, University of Florida, to develop a simulation model for the education in the physiology, detection, and management of venous air embolism. Venous air embolism is the introduction of atmospheric air into the bloodstream of a patient, which can result in hypoxemia, hypotension, electrocardiographic changes, altered mental status, stroke, unconsciousness, cardiac arrest, and death.

Air entering the bloodstream is usually iatrogenic, meaning it is introduced by a medical provider as a direct result of a medical intervention that in many cases is preventable. It can be introduced through any existing intravenous access (peripheral IV line, central line, PICC line), through surgical incision, through any procedure that might damage a vein or artery (endoscopy), or through traumatized vessels (trauma patient). Venous air embolism has resulted in significant morbidity and mortality in the modern medical era. A lack of awareness of the presence and complications of venous air embolism by providers has resulted in MPL actions for failure to diagnose, treat, and, most importantly, prevent their occurrence. In her Smith Award project, Dr. Le-Wendling created an online educational module to teach medical staff preventive measures and improve an understanding of venous air embolism and why it is important to reduce its occurrence. Using a graph representation model in an animated video, the education module addresses possible scenarios and ways to detect and diagnose venous air embolism, as well as a management algorithm. Post-test development was designed to confirm knowledge retention and awarding of CME credit. Upon completion of provider education, a review of patient records measures the incidence of venous air embolism before and after implementation. It is anticipated that the data analysis will reveal that this new CME has resulted in a lower incidence of air embolism and improved patient outcomes.

Multiple stakeholder benefits

Although the Smith Awards were developed in an academic medical setting, the concept is being adapted for a variety of healthcare venues, such as long-term and ambulatory-care settings. Modest funding by MPL carriers provided to their insureds' locally focused projects represents a joint investment in patient safety and claim reduction initiatives. Collaboration among business partners who share similar goals and objectives, such as the University of Florida Self-Insurance Program and Continuing Medical Education Office, can exponentially increase the opportunities for provider projects. Patients are crucial beneficiaries of these projects by way of safer, more effective care. Providers and facilities gain the benefits of higher patient satisfaction, fewer adverse events, and lower premiums for sustained loss prevention improvements. MPL insurers can realize reduced claims and improved loss results; they also demonstrate their ongoing trust in their insured providers: in their success, ingenuity, and commitment to excellent patient care.

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Keeping Up with HIPAA

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The Department of Health & Human Services (HHS) released the HIPAA Omnibus Rule in January 2013 which modified the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules.

The HIPAA Omnibus Rule final rule implemented most of the privacy and security provisions of the HITECH Act and extended the reach of HIPAA. With a few exceptions, organizations were required to be in compliance with the final rule by September 23, 2013.

Although many HIPAA provisions haven't changed, the final rule made some significant changes that affected covered entities, business associates, and subcontractors of business associates. Specifically, there were significant changes to the breach notification standard, certain HIPAA provisions now apply to Business Associates and their subcontractors, patients now have enhanced rights to access their Protected Health Information (PHI) and to restrict the disclosure of their PHI, the rules regarding the use and disclosure of PHI were adjusted, and notably, the government's ability to enforce HIPAA has been enhanced.

Breach notification.

HHS eliminated the "harm threshold" provision from the Breach Notification Rule. Under that provision, covered entities were only required to provide notice of a security breach if it posed a significant risk of harm to the affected individuals. Under the final rule, any use or disclosure of PHI that is not permitted by the Privacy Rule is presumed to comprise a breach. A breach is generally an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of PHI unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the PHI has been compromised based on a risk assessment.

In instances where a breach has occurred, a covered entity must conduct a risk assessment and consider the factors set by HHS, which include: assessing the nature and extent of the PHI involved, identifying the unauthorized person who used the PHI or to whom the disclosure was made, determining whether the PHI was actually acquired or viewed, and finally, determining the extent to which the risk to the PHI has been mitigated Changes to the definition of a breach may mean that covered entities will see an increase in the number of breaches that must be reported to HHS.

Stronger requirements for Business Associates and subcontractors.

Much of the Privacy Rule and all of the Security Rule now apply directly to both Business Associates and their subcontractors. A "business associate" is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to PHI. A "business associate" is also a subcontractor that creates, receives, maintains, or transmits PHI on behalf of another business associate.

Business Associates and their subcontractors are now responsible for creating and implementing HIPAA compliance plans if they didn't already have one in place. Also, Business Associates must also conduct a thorough risk analysis of information systems containing electronic PHI.

New limits on uses and disclosures of PHI.

The final rule addressed a number of privacy issues related to the uses and disclosures (sharing) of PHI, such as communications for marketing or fundraising, exchanging PHI for remuneration, disclosures of PHI to persons involved in a patient's

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care or payment for care, and disclosures of student immunization records.

One pleasant surprise for the health care industry was the expansion of the use and disclosure of PHI for fundraising purposes. Previously, a covered entity could use or disclose only demographic information and dates of service for fundraising purposes. The final rule expanded the categories of PHI that may be used and disclosed to allow for targeted fundraising communications.

The new categories of PHI that may be used for fundraising now include: department of service, identity of the treating physician, general outcome information and health insurance status.

Another positive change affects clinical research. The final rule allowed a blending of "conditioned" and "unconditioned" authorizations into a single document. The bottom line for those conducting research is that this change simplifies authorization paperwork.

A challenge presented by the new HIPAA rules consists of additional restrictions on marketing and sale of PHI. The final rule expanded what uses and disclosures of PHI are considered to be "marketing" and therefore require a patient's authorization.

Expanded focus on patient rights.

The final rule expanded patients' rights to access electronically stored PHI. Organizations are required to give patients their medical record in the form and format requested, if readily producible. If the medical record is maintained electronically, then covered entities must provide patients an electronic copy at the patient's request. Also, a patient may designate a third party to receive a copy of his or her PHI. The request must be in writing, clearly identify the designated person, and clearly identify where to send the copy.

The final rule also established that covered entities may charge patients a "reasonable, cost-based fee" for the release of electronic medical records. A covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of labor for copying the PHI requested, supplies for creating the paper copy or electronic media (if the patient requests that the electronic copy be provided on portable media), postage, and preparing an explanation or summary of the PHI. The reasonable, cost-based fee excludes charging patients for certain items, such as the records search, retrieval of the file, and other administrative costs.

Restriction for out-of pocket payments.

The final rule also allowed patients to restrict information for items or services paid out-of-pocket. Covered entities must agree to a patient's request to restrict disclosure of PHI to a health plan if the healthcare item or service has been paid out-of-pocket and in full, unless the disclosure is required by law. This applies if a patient or other person on the patient's behalf pays for the item or service. Healthcare organizations must also recognize this type of restriction request if audited by a health plan, since there may be patient information that should not be disclosed to the health plan.

Notice of Privacy Practices.

The final rule changed the requirements for what organizations must include in their Notice of Privacy Practices. Updated notices must advise patients of required changes in the final rule, including:

- The prohibition on the sale of PHI without the written authorization of an individual
- The duty of the CE to notify affected individuals of a breach of unsecured PHI
- The patient's right to opt out of receiving fundraising communications
- The right to restrict disclosure to a health plan when the patient pays out-of-pocket

The final rule made it clear that genetic information is also included in the definition of "health information" and is subject to HIPAA rules. Under GINA, healthcare plans are prohibited from using and disclosing genetic information for underwriting purposes.

Increased enforcement.

The HIPAA Enforcement Rule contains provisions relating to compliance and investigations, the imposition of civil money penalties for violations of HIPAA, and procedures for hearings. One of the ways that OCR carries out this responsibility is to investigate complaints filed with it. OCR may also conduct compliance reviews to determine if covered entities are in compliance and the OCR performs education and outreach to foster compliance with requirements of the Privacy and Security Rules.

Some of the significant modifications to the HIPAA Enforcement Rule include provisions

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that affected OCR compliance investigations, the imposition of civil money penalties (CMPs), liability of covered entities for acts or actions by business associates, liability of business associates for acts or actions of their contractors, and mandatory civil monetary penalties for violations due to willful neglect.

Business associates and their subcontractors are now subject to CMPs and other enforcement actions for noncompliance with applicable provisions of HIPAA. Also under the final rule, the OCR will investigate all cases of possible willful neglect, defined as a "conscious, intentional failure or reckless indifference" to the obligation to comply with HIPAA. OCR will impose a penalty for all violations of willful neglect.

A table describing the various tiers of civil money penalties is shown below.

HIPAA Violation Category	Each Violation	Total CMP for Violations of an Identical Provision in a Calendar Year
Individual did not know	$100 - $50,000	$1.5 million
Reasonable Cause	$1,000 - $50,000	$1.5 million
Willful neglect - corrected	$10,000 - $50,000	$1.5 million
Willful neglect – not corrected	At least $50,000	$1.5 million

NICA – Florida's Innovative Alternative to Costly Litigation

Kenney Shipley, Executive Director
Florida Birth-Related Neurological Injury Compensation Association

It has been 25 years since The Florida Birth-Related Neurological Injury Compensation Association (NICA) was established to help curtail the unpredictable cost of covering certain catastrophic birth injuries in the tort system. The statutory plan was designed as a no-fault system to save hospitals and physicians' malpractice costs and provide a better, faster and more reliable compensation structure for infants with certain neurological injuries. Any risk manager who has had a claim accepted for coverage by NICA, whether insured or self-insured, should be able to tell you that it is a better alternative. Of 116 hospitals that provide obstetric services all but 13 have had NICA claims accepted, and although the average cost for NICA for lifetime care for a brain injured child is $4.9 million, this is money that actually goes to the care of the child and to give the family stability. On an incurred basis, NICA pays less than 1% in attorney fees. Now think of the cost of one of these injuries in the tort system. In recent years, these have resulted in damages of $20 million and up according the Florida Office of Insurance Closed Claim Database with one settlement (not a verdict) amounting to $149 million. It is nearly impossible to predict, plan and insure for these claims. What is worse, a large percentage of the money from these settlements and verdicts go to the plaintiff attorney, sometimes leaving the family with much less than is needed to care for the affected child.

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In case you have been fortunate enough not to have been involved in a NICA claim, this is how it works. We usually receive the first notice when a parent, the petitioner, files a petition with the Division of Administrative Hearings (DOAH) in Tallahassee. We provide the information and the form necessary to file on our website and will even pay the $15 filing fee if the petitioner is pro se and can't afford it. Sometimes we hear from a hospital risk manager or an obstetrician about a possible claim, and we recommend that they have the patient contact us if possible. We can't actually open a claim until a petition is filed at the Division and served on us, but we can open a "potential" claim, and can talk to a pro se petitioner and help them through the process.

If there is an attorney involved, usually we get it after suit has been filed and the hospital or physician has moved to have a circuit court case abated until a NICA determination is made. Motions for abatement on these cases are granted almost 99.99% of the time if there is any allegation of a birth related injury, even if it is pretty obvious that they won't meet the statutory threshold. It is solely in the jurisdiction of the administrative law judge (ALJ) to make a determination of whether or not there is a qualifying injury. You can view the motion template and supporting case law used to assist in getting an abatement on the NICA website: https://www.nica.com/hospitals/abate.html

A petition is served on all parties by the ALJ, and this is the only notification any of the parties, other than NICA and the petitioner, will receive until a final order is issued. The only exception would be is if a motion to intervene in the proceedings is filed. Most hospital counsel are well aware of this and either intervene or follow the case on the DOAH website until a determination has been made by the Administrative Law Judge. DOAH is paperless, and all pleadings are available online, usually within a few hours after filing. It is an easily searchable website (http://www.doah.state.fl.us/ALJ) and allows interested parties to monitor and research cases.

NICA notifies involved physicians in writing and explains the process to them. Often the hospital and/or physician will wait until NICA files a response and will only intervene if they disagree with the NICA position or feel there are additional issues not recognized or raised by NICA.

Florida law requires that participating physicians and hospitals with participating physicians on staff provide notice to the obstetrical patients of the NICA plan and if there is a question about whether or not proper notice was given, the hospital or physician must intervene to defend that issue as NICA does not have the evidence necessary to do so.

Upon receipt of a petition, a review is conducted by the Executive Director and the Nurse Case Manager who handles intake. A request is made for the maternal and infant medical records which are sent to a maternal-fetal specialist for an opinion as to whether there was an obstetric event. If the answer is in the affirmative, an appointment with a pediatric neurologist is scheduled to perform an independent medical examination to determine whether there is an injury that rises to the statutory requirement, i.e. injury due to loss of oxygen or hypoxia, a mechanical injury, or a permanent and substantial physical and mental impairment. Based on their opinions, NICA files a response either accepting or denying the claim.

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— Kenney Shipley

A large majority of claims are relatively easy to determine from a review of the clinical record. Many times NICA findings support the petitioner's claim and a stipulation is entered into accepting the claim and eliminating the need for a hearing. NICA files the stipulation and usually within a week to two an order allowing NICA to begin compensation is received. Cases that have disputed facts usually go to hearing. Although there is discovery and often depositions involved in the hearing process, it is a much more efficient process than circuit court. The hearing is before an ALJ so the discovery process is quite a bit

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more informal, and hearings are scheduled quickly. Hearings generally last a few hours to one day. Even when there are disputed issues, the average time to resolve a NICA case is about 180 days. Some take longer, but the vast majority are handled in a timely manner.

The most frequent problem encountered with a claim is failure of the hospital or physician to give timely notice and document both through written procedures and by having the patient sign an acknowledgement form saying that they have received the brochure printed by NICA which must be provided by the hospital and physician.

— Kenney Shipley

The most frequent problem encountered with a claim is failure of the hospital or physician to give timely notice and document both through written procedures and by having the patient sign an acknowledgement form saying that they have received the brochure printed by NICA which must be provided by the hospital and physician. A signed acknowledgement form creates a rebuttable presumption that notice has been given. Case law is well settled in the Bennet v. St. Vincent's Medical Center case as to what "timely notification" means. You can find a copy on the DOAH website of the Supreme Court Case under DOAH Case # 06-2422. It is a very fact- based issue decided by an ALJ who has sole authority to determine whether proper notice has been given. There is only one ALJ at any given time who handles all NICA cases. While best practices require that a signed acknowledgement form be obtained from the patient and carefully retained, even in the absence of that form, evidence can support that the brochure was properly given.

The current ALJ issued an order in a recent case which illustrates well what physicians and hospitals are expected to do to demonstrate that proper notice was given in the absence of the actual signed acknowledgement form that couldn't be found in the clinical record.

This case is also available on the DOAH website under the Final Order on Notice that is posted for Case # 13-3287. Although the physician was unable to produce a signed form in this case, there was testimony from the Physician's Assistant about what is routinely done with each new obstetric patient, the forms routinely included in the packet given to a new obstetric patient, the time always allocated to a new obstetric patient and the person that always talked to new obstetric patients. There was also testimony about all of the subjects discussed at that appointment, including NICA. Although the petitioner in this case disputed the testimony and gave conflicting testimony, the PA's testimony in conjunction with the appointment records from the office were credited by the ALJ who found that timely notice had been given as soon as the physician/patient relationship was established.

There was also conflicting testimony and evidence regarding the hospital's notice in this case. Notice must be given "as soon as practicable" upon initiation of the patient/provider relationship and in this case, the petitioner had visited the emergency room several times before her admission for labor, and had taken a tour of the hospital several months prior. Each of the hospital visits were either for unrelated health issues or for out-patient lab work or ultrasound. The ALJ concluded that none of these established the relationship as an obstetric patient. There was conflicting testimony as to whether the petitioner pre-registered. She stated that she had filled out paperwork and pre-registered at the time of one of her outpatient visits. The hospital had detailed records of how pre-registration is conducted, and what entries are made to the hospital system in the case of a pre-registration, as well as how accounts are set up for the different types of visits. Again, because the hospital had detailed procedures in place and was able to document the differences, even absent a signed acknowledgement form, the ALJ found that proper notice had been given by the hospital.

Benefits

Once a claim has been approved, NICA provides anything that is "medically necessary and reasonable" for the child for the rest of his or her life. This term

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is very broadly construed by both NICA staff and the ALJ in case of a disagreement over benefits. If there is a Medicaid lien, it is withdrawn – NICA is not a "third party" for the purposes of collecting a Medicaid lien. There is a $100,000 lump sum paid to the family or on behalf of the family as directed. A NICA Nurse Case Manager is assigned and available to the family every day. NICA staff visit the family to ascertain needs, and can even pay the family in lieu of a private duty nurse to help care for the child. Most children need some level of nursing care which is provided in the home. We arrange for therapies without a numerical limitation, cover deductibles and pay for drugs, equipment, even spas and vans for children. NICA gives the family some level of financial security and support for the very complex needs of these children. There are no arbitrary caps or limitations.

NICA is efficient both from a legal process or litigation standpoint and as a mechanism to support and compensate children with very complex injuries. Although 25 years old, NICA remains one of the most innovative programs in the American system of jurisprudence. While disliked and opposed by many plaintiff trial lawyers, there are some that recognize the long term benefits it provides for the child and their family, and the ease of determination. If you have questions about NICA I would be very happy to answer them and provide in service training. Please look at our website at www.nica.com, and give me a call any time.

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Risk Rx, which we have provided to our Self- Insurance Program participants for over a decade, gives us an opportunity to communicate with you on a quarterly basis about the many issues impacting healthcare providers. Our intent is to share and promote useful subject matter and strategies to enhance patient safety, prevent loss, and minimize exposure to liability.

-Jan Rebstock, RHIT, LHRM, CPHRM
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