EXECUTIVE SUMMARY

Pursuant to AHCA Contract #A0408, the University of South Florida submits this Final Report which presents recommendations proffered by the Workgroup of Medical Malpractice Litigation Alternatives, as these relate to the implementation of the Florida Patient Safety Corporation.

In February of 2004, the Florida Patient Safety Academic Task Force, consisting of the University of Florida, University of Miami, Florida State University, Nova Southeastern University and the University of South Florida, produced the Section 35 and Section 36 Reports to the Agency for Healthcare Administration and the Florida Legislature. These reports provided recommendations for the steps that could be taken by Florida to reduce medical errors, improve patient safety, and as a consequence, effect a change in the devastating rate of medical malpractice insurance and litigation-related costs.

In March, AHCA continued the Legislative mandate by requesting a set of studies to provide recommendations for implementing the findings of the Section 35 and 36 reports, specifically, how the newly created Florida Patient Safety Corporation can develop a research and programmatic agenda around medical malpractice litigation alternatives.

The recommendations below are the findings of 100 days of collaborative meetings, research review and thoughtful discussions among a Workgroup consisting of representatives of the Florida's hospital and medical associations, the medical malpractice liability insurance industry, managed health care, trial attorneys, health care industry...
consultants, academic patient safety centers and regulators. These recommendations are intended to serve part of a template to guide the start-up efforts of the new Corporation.

**Workgroup Recommendations:**

1. The Workgroup unanimously agrees that the best alternative to litigation is no litigation at all.
2. With respect to the panoply of underwriting issues, the Workgroup was unanimous in its recommendation that malpractice insurance carriers need to better educate providers, policy makers and consumers about the realities of underwriting and the time lags that exist between the introduction of a new strategy and the measurement of results within an affected population.
3. In light of the short duration of PSC funding from the Legislature, the Workgroup members unanimously endorse immediate efforts of the PSC to seek additional, external sources of research and programmatic support from public and private funding sources through aggressive efforts to write and execute grant and contract proposals.
4. The Workgroup notes that the new PSC should be especially sensitive to the distinctions between medical negligence and bad outcomes.
5. The Workgroup recommends that retrospective and prospective studies be conducted to assemble background data using large samples of closed claim cases. A demonstration research project could then be conducted using these data. An applied alternative discussed by the Workgroup is the use of a mock medical court, comprised of physicians, nurses, attorneys and possibly consumer members.
6. The PSC should conduct comprehensive studies and prepare compilations of factual information that could be incorporated into a handbook or a consumer guide to the law, for patients, family members and physicians about how the system works, legal options available to them, questions they should ask, etc. A good starting point for such a guide would be the State of Florida standard jury instructions. These data and findings should be shared in an accessible form with consumers, providers and policy makers.
7. The Workgroup recommends that efforts be made to create incentives within all sectors of the health care system (hospitals, clinics, physician offices, pharmacies, etc.) to report adverse events promptly and completely.
8. The PSC should conduct research to reduce the conflicts of interest between and among the regulatory entities (Boards of Medicine, Osteopathic Medicine, Nursing, Dentistry, Podiatry, Chiropractic) in order to create a learning environment, rather than a punitive environment around patient safety.
9. The PSC should examine the risks and benefits of creating appropriate regulatory safe harbors for reporting of adverse events.
10. The Workgroup recommends that there should be new provisions for the protection of pre-suit offers of settlement, thereby likely creating incentives to early settlement in meritorious cases.
11. The Workgroup recommends that the PSC should compile evidence regarding programs such as the Colorado based medical liability insurance entity, COPIC, which has diversified insurance, brokerage and risk management products and services, and its effectiveness in reducing incidents and claims.

12. The PSC should examine the use of periodic payments, structured settlements, the creation of trusts, and other financial mechanisms that are intended to effectively and efficiently compensate persons who are injured.

13. The PSC should collect and maintain incidence and prevalence data about adverse outcomes, by disease, illness, disability and injury category.

14. The Workgroup recommends that enhancing the underwriting process within medical malpractice insurers (both commercial and self funded) as a component that could contribute to the reduction of adverse outcomes and medical malpractice litigation.

15. Workgroup members endorse empowering practitioners by giving them data about themselves, relative performance with peers, and broader institutional, regional and national outcome expectations and realities.

16. The PSC should assume a leadership role in encouraging the creation of educational programs for clinicians and the dissemination of relevant best outcome data and risk management processes to clinicians.

17. Workgroup members caution about the adoption by the PSC of best practice or evidence based medicine practices or guidelines in Florida. Emphasis should be placed on best outcomes.

18. Workgroup members stress the importance of ensuring that any data and any reports issued by or through the PSC are accurate and credible.

19. The PSC should encourage active, direct involvement of third party insurers and managed care companies in the development of programs that create incentives for physicians and hospitals to improve patient safety and reduce medical errors.
INTRODUCTION

Florida Senate Bill 2D (2003) resulted in the production of Section 35 and Section 36 reports on patient safety to the Agency for Health Care Administration and the Florida Legislature by the Florida Academic Task Force on Patient Safety. Following the submission of these reports, which provided the basis for the creation of the newly formed Florida Patient Safety Corporation (PSC), the Legislature requested a set of studies to provide guidance on the implementation of the new PSC. This report was commissioned to provide recommendations regarding the introduction of risk management and best practices/best outcomes within the health care system that could contribute to a reduction in adverse events that cause medical malpractice claims.

A cross-industry Litigation Alternative Workgroup was formed to provide guidance on how litigation in medical malpractice can be reduced through front-loaded, preventive, risk management efforts; and post adverse event, through alternatives to traditional litigation. The Workgroup’s efforts, summarized here, build upon the Section 36 final report issued to the ACHA and the Legislature on 1 February 2004. The Workgroup has held three on-site meetings (Tallahassee, Tampa and Ft. Lauderdale) and has held six sets of telephonic conference calls over a 100 day period. Background activities of the Workgroup included research coordinated by the members of the Academic Patient Safety Network, consisting of the University of South Florida, the University of Miami, the Florida State University, Nova Southeastern University and the University of Florida.

In the conclusion to the Section 36 Report on Litigation Alternatives the Academic Task Force stated:

Patient safety improvement is a key to reducing the many burdens of medical malpractice, including the burden of errors that cause injuries to patients and the burden of litigation. Throughout the process of health care delivery it is possible to reduce error and improve care outcome. This alone will provide the best and most cost effective litigation alternative. But when errors do occur and cause
injury, then the health care system must behave differently than it does today in order to quickly, transparently and equitably remediate the injury to reduce the costs, time and anguish of litigation. This requires a cooperative, collaborative venture among health care providers, patients, insurers, attorneys, regulators and legislators. We are all in this together. (Section 36 Final Report, Page 286)

Since the publication of the findings of the Academic Task Force, the Florida Legislature enacted and the Governor signed a law establishing the Florida Patient Safety Corporation, a not-for-profit, non-regulatory entity intended to promulgate a learning culture of patient safety among patients, physicians, hospitals, insurers, attorneys and regulators.

The express purpose of the Workgroup has been to provide a working template for the newly created Florida Patient Safety Corporation's (PSC) research and programmatic initiatives. The short duration of PSC funding and close deadline for expected PSC products demand that the parties vested in patient safety improvement in Florida have a running start on implementing the Legislature’s intentions with respect to the PSC.

The Workgroup developed its recommendations based upon the following outline questions:

- How can best outcomes and risk management strategies be incorporated into the clinical operations and regulatory policies affecting health care providers and liability insurance carriers in Florida?
- How can the PSC work with malpractice insurance carriers, provider hospitals and clinicians to determine how risk management, risk reduction and clinical best practices/best outcomes may be inserted into the operations of health care organizations through enhanced, collaborative efforts?
- How can the PSC work with managed health care and other third party organizations to create incentives for implementing patient safety systems and programs?
• How can the PSC work with liability carriers, attorneys, consumer groups and providers to identify and encourage appropriate administrative and legal alternatives such to traditional litigation, such as more aggressive use of arbitration, mediation, structured settlements\(^1\), trusts and “no-fault”\(^2\) concepts?

The formation of a litigation alternative workgroup built upon the relationships and activities established during the research effort that culminated in the production of the Section 35 and Section 36 reports. Representatives of health care providers, malpractice insurance carriers, trial attorneys, health care industry consultants, Florida Office of Insurance Regulation officials, third parties, and academic medical centers were brought together to form a workgroup to review research, practice and practical options that could lead to alternatives to medical malpractice litigation.

At the outset of this effort, the Workgroup members unanimously agreed that the ideal alternative to litigation was no litigation resulting from fewer medical errors. The Workgroup linked post adverse events ("backend") litigation alternatives directly with preventive risk management and best outcome efforts front loaded into the health care system. The group developed recommendations designed for the new Patient Safety Corporation that could serve as a template for improving risk management, encouraging and helping to create better outcomes, providing incentives to providers through reimbursement, and offering options to traditional litigation post adverse event.

A designated core group was established to facilitate the Workgroup's activities. The core group consisted of:

- Martin Smith, Director Self Insurance Program, University of Florida
- Steven Stark, Esq., Fowler, White, Burnett, PA, Miami
- Lynn Glass, BSN, JD, Self Insurance Program, University of Florida

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\(^1\) Structured settlements include alternative payment methods, such as annuities and periodic payments.

\(^2\) “No Fault” represents a category of insurance benefit in which all persons experiencing a type of injury are provided some compensation for their injury, regardless of whether the tortfeasor, or alleged person causing harm, has liability insurance and regardless of who was to blame for the injury. No fault insurance programs are common within automobile liability plans and workers compensation plans in Florida and other states. There are limited no-fault medical malpractice liability insurance systems, including one in Florida called the Neurological Injury Compensation Act (NICA), referred to elsewhere in this report, which provides coverage for limited cases of neurological injuries in newborn children. Only New Zealand has a comprehensive no-fault medical malpractice insurance plan.
Les Beitsch, MD, JD, Florida State University, College of Medicine Center for Patient Safety
Nir Menachemi, PhD, Florida State University, College of Medicine Center for Patient Safety
Paul Barach, MD, MPH, University of Miami, College of Medicine, Center for Patient Safety
Trevor Smith, Reverly Resources
Michelle Maynard, MBA, TVC, a process improvement consultancy
Jay Wolfson, DrPH, JD, University of South Florida, Suncoast Center for Patient Safety

Staff for the workgroup consisted of:
Robin Suggs, Project Coordinator
Marie Denis, Research Assistant
Andrea M. Spehar, DVM, MPH, JD, Research Assistant Professor

Other members of the Workgroup consisted of:
Glen Davis, MD, Florida Medical Association
David McKalip, MD, Florida Medical Association
Karen Peterson, Esq., Florida Hospital Association
Bill Bell, Esq., Florida Hospital Association
Sam Kaplan, Independent Health Benefit Consultant
Kurt Driscoll, Florida Physicians Insurance Corporation (FPIC)
Cliff Rapp, FPIC
Deborah Zappi Henley, Esq., Academy of Florida Trial Lawyers
David McKenney, Pro National Assurance
Thomas Kernan, Marsh
Barry Anderson, University of South Florida Self-Insurance Program
Jack Osgard, University of Florida Self Insurance Program
John Knight, Florida Medical Association
Richard Koon, Florida Office of Insurance Regulation
Web Brennan, Esq., Academy of Florida Trial Lawyers.
William Wood, MD, Blue Cross Blue Shield of Florida
Jeff Scott, Esq., Florida Medical Association
Robert Sutton, MD, AvMed

Scheduling of Workgroup meetings proved to be a challenge because the Florida Legislature was in session during much of the early portion of the contract period, and many representatives of the above vested parties were not easily available. Phone conferences were convenient and successful means by which Workgroup members were able to communicate, share ideas and reach consensus about the topics they would focus upon.
To the best of our knowledge, this was the first time that a group of people representing these diverse organizations and interests was brought together, for a protracted period of time to discuss the nexus of litigation alternatives and medical errors. Participants in this Workgroup process agreed that the recurrent interaction among the same group of individuals helped to break down stereotypical barriers that had made communication and agreement on these issues difficult in the past. The frequent meetings, by telephone and in person succeeded in establishing and maintaining new relationships that helped to build trust. The value of this foundation of trust is reinforced by the fact that many of these same individuals will be playing direct roles either as members of the board of the new PSC or as members of advisory committees.

Following an initial conference call on 19 March 2004, an outline for research and meeting progress was established. An e-mail listserv was created through which members of the Workgroup could communicate.

The first Workgroup meeting was held in Tallahassee on 16 April 2004 at which research findings and Workgroup goals and objectives were reviewed. The Workgroup consisted of individuals representing many of the organizations that are named to sit on the newly formed Patient Safety Corporation (which at the time was still being designed by the Legislature) or its various advisory committees.

At this first meeting substantive discussion about the role of best practices/outcomes and the value of structured settlements, no-fault insurance and trusts dominated the several meetings and phone conferences of the Workgroup. The Workgroup sought to focus on potential PSC process – that is, how could the new PSC best get off the ground and address these issues without getting bogged down?

Workgroup telephone conference calls were held on 19 March, 26 March, 3 May, 17 May, 9 June and 10 June 2004. The Workgroup was divided into three teams to
separately address each of three foci: best outcomes/risk management strategies and incentives by malpractice insurance carriers; post litigation alternatives; and incentives by third parties and managed care organizations.

Underwriting issues of malpractice insurance carriers were highlighted at the second meeting of the Workgroup in Tampa on 19 May 2004. Finding ways by which to effectively translate known best practices into premium discounts were discussed. The emphasis continued to focus on creating a process by which the proposed Patient Safety Corporation could develop research and programmatic activities to effectively address this topic. With respect to the panoply of underwriting issues, the Workgroup was unanimous in its recommendation that malpractice insurance carriers need to better educate providers, policy makers and consumers about the realities of underwriting and the time lags that exist between the introduction of a new strategy and the measurement of results within an affected population.

Research was initiated into the following topics:

- Efforts of other insurance lines (workers compensation, general liability, auto, etc.) to include premium discounts/reduction programs based on the insureds having adopted and implemented certain risk reduction strategies.
- Evidence from other states to create incentives or require that insurers provide discounts to insureds (in any insurance line) if the insured adopts and implements certain risk reduction strategies.
- The use of trusts and structured settlements as alternatives to litigation solutions.
- How managed health care organizations and health insurance carriers are creating incentives to providers to enhance patient safety by reducing the likelihood of adverse events.

Information obtained about these topics was periodically forwarded to Workgroup members by e-mail. The results of this research were also discussed within the Workgroup at phone conferences and at meetings.

The National Association of Insurance Commissioners provided summary data about the statutory and regulatory provisions for best practices that affect automobile insurance
They had no data on any other insurance products. (Appendix A) The Florida Office of Insurance Regulation provided summary data on efforts nationally to create incentives within Workers' Compensation insurance product lines. (Appendix B) Research into other insurance lines indicates that there are a variety of principally voluntary provisions across the nation in general casualty and liability products that seek to encourage certain categories safe practices, safe outcomes within the various insureds. (Appendix C) It is common for automobile liability policies to offer rate reductions for under 21 or 25 year old drivers who can demonstrate that their grade point averages are above a certain level because there is a correlation between better grades and safer drivers, in general. Workers Compensation and general casualty and liability insurance carriers include technical site assessments, employee screenings (i.e. for substance abuse) and other measured efforts to encourage specific safety enhancement/improvement practices.

The final meeting of the workgroup was held on 16 June 2004 in Ft. Lauderdale. It produced a draft summary of recommendations for the PSC that serves as the basis for this draft final report.

WORKGROUP FINDINGS AND RECOMMENDATIONS

FOCUS ON PROCESS NOT PRODUCT

The Workgroup members are unanimous in recommending that the initial efforts of the newly formed Patient Safety Corporation should focus on the process of addressing improved patient safety and reduced medical errors, rather than on specific products. This process should consist of research inquiries and assembling information that can be used by patients, families, providers, attorneys and policy makers to better understand the opportunities to improve patient safety and reduce medical errors. A rationale for focusing on process over product was that there remain highly charged, divergent views across the various groups of physicians, trial attorneys, hospitals and insurance carriers. Another reason is the magnitude of extant data and processes already available but
requiring substantial research attention. The PSC should assess and evaluate the panoply of existing information and reporting systems before seeking to create a new one out of whole cloth.

In light of the short duration of PSC funding from the Legislature, the Workgroup members unanimously endorse immediate efforts of the PSC to seek additional, external sources of research and programmatic support from public and private funding sources through aggressive efforts to write and execute grant and contract proposals.

To accomplish this, the Workgroup recognizes the value of building upon the accumulation of research, including the recently completed Section 35 and 36 Studies performed by the Academic Task force, data provided by the National Association of Insurance Commissioners, the Florida Office of Insurance Regulation, and reviews of statutory and regulatory provisions across the States, and review of published research.

This does not preclude the high priority goal of creating the foundation for a state-wide near miss reporting system. The creation of a viable patient safety improvement entity in Florida and a reporting system can take from three to five years. The first year is critical to establish the momentum and the commitment to a highly successful, well recognized, public private partnership. This in turn, can provide the synergy to create a national model to reduce litigation and costs associated with medical malpractice.

**POST ADVERSE EVENT LITIGATION ALTERNATIVES**

The Workgroup unanimous agrees that the best alternative to litigation is no litigation at all – by creating a health care system that is free from medical error and adverse events. Frontloading the system with best outcome orientations and risk management strategies is therefore the preferred method to reduce litigation. When there is an adverse event, however, the goal should be fair, uniform, predictable and rapid resolution of claims.
The Workgroup notes that the new PSC should be especially sensitive to the
distinctions between medical negligence and bad outcomes. Bad outcomes are the
result of the natural course of an illness, disease, disability or injury – not the result of a
negligent clinical action. Some members believe that some lawsuits are "frivolous", an
incendiary term that is frequently used in the press and spoken in public. While there is
great emotion around the issue, there is a dearth of empirical evidence that frivolous
actions abound, and the trial bar notes that it is a disservice to suggest otherwise. There
may be issues of poor science being introduced in support of certain cases – but this does
not make the cause of action frivolous – it speaks instead to the standard of evidence used
in state courts and the fact that in a few cases expert witnesses on both sides may abuse
good science. The trial bar acknowledged that there is a difference between negligence
and bad outcomes, and noted that the costs of bringing suit can easily reach a minimum
of $100,000 that is often not reimbursed for years as the case travels through the system.
With this cost in mind, trial bar members felt that most legitimate plaintiffs’ attorneys
effectively pre-screen their clients and reject most of the cases, even though meritorious,
that come to them for one of two reasons:

1) There is no cause of action under Florida Law, such as the wrongful death
medical malpractice exemption, at. s.768.21(8) F.S.; the statute of limitation has run;
and/or there is questionable liability, i.e., it is not apparent that a health care provider fell
below the standard of care.

2) The injury sustained represents such a low economic value that initiating
any action would cost more than could be recovered for the client.

Trial bar representatives noted that they would prefer to see their colleagues who initiate
questionable actions removed from the market.

The issue of low-end economic damages re-ignited discussions about the value of a no-
fault option. The Workgroup referenced the substantive discussion of no-fault options
that was included in the Section 36 Report of February 2003. The Workgroup recognizes
that there are substantial trade-off costs that could inundate any system if all injuries were subject to no-fault compensation. While screening systems, such as medical courts, might help to sort out the “bad medical outcome” cases from the bona fide medical negligence cases, the combination of screening costs and the likely increased net payouts associated with a no-fault approach would require sources of compensation that are much higher than those available in the marketplace today. There was concern among parties about the risk of creating a new “gaming” system around a no-fault approach similar to what some believe occurs within workers compensation and automobile liability no-fault systems. The trial bar is not alone in questioning the viability of expanding no-fault into medical malpractice. The majority of members of the Workgroup expressed serious reservations about any no-fault expansion. Indeed, in Florida and elsewhere, some policy makers and insurers have questioned no-fault automobile and workers compensation insurance, arguing that it has merely created an administrative system for providing certain compensation for a large number of injuries at costs that may not justify the process.

Nonetheless, some members of the Workgroup believe that there is value in examining some expanded form of the NICA model of no-fault, particularly as it may relate to specific categories of injury, where the incidence of misdiagnosis is high, and where establishing negligence is difficult.

While the general tenor of the Workgroup disfavored no-fault expansions at this time, hypothetical discussions were held about how no-fault might be demonstrated or tested. Breast cancer misdiagnosis was raised as one of the most common categories of misdiagnosis – and some members were interested in discussing how compensation could be made less cumbersome through no-fault. There was no agreement on this matter. But there was unanimity that research be conducted by the PSC on closed claims data to better understand what kinds of cases might be amendable to alternative compensation.
The Workgroup recommends that retrospective and prospective studies be conducted to assemble the background data on large samples of closed claim cases. A demonstration research project could then be conducted using these data. An applied alternative discussed by the Workgroup is the use of a mock medical court, comprised of physicians, nurses, attorneys and possibly consumer members. The trial bar does not agree that that this type of second guessing of cases by medical courts should be done because the information available to re-evaluate the case would not be complete, and many of the settlements are confidential. The trial bar does not support this proposal, noting that only a judge and a jury who have heard the evidence, witnessed demeanor, etc. are in a position to re-address liability and damages. Other Workgroup members believe that such mock courts would be beneficial in helping to determine the relative differences in findings and the costs that might accrue to the system if a constructed set of no-fault rules were to be applied (such as fee schedules and limitations on non-economic damages). A demonstration of this nature would require at least two years of effort, and would be a subject for external funding. The results of these studies could augment future discussion of no-fault options in Florida.

The PSC should also conduct comprehensive studies and produce a compilation of factual information that could be incorporated into a handbook or a consumer guide to the law, for patients, family members and physicians. This product would provide clear, unequivocal information about how the system works, options at law available and questions people should ask. A good starting point for such a guide would be the standard State of Florida jury instructions.

The guide should include, but not be limited to:

- a thorough review and publication of Florida common law, statutes and constitutional requirements regarding compensatory damages;
- pre-suit processes;
- periodic payments;
- annuities;
- special needs trusts;
- collateral sources;
• attorney fees;
• partial lump sum payments;
• the entire concept and practice of present value determinations;
• guardianship; and
• other relevant, timely topics.

These data and findings should be shared in an accessible form with consumers, providers and policy makers. This effort should require less than one year of research and compilation.

The Workgroup recommends that efforts be made to create incentives within all sectors of the health care system (hospitals, clinics, physician offices, pharmacies, etc.) to report adverse events promptly and completely. But to accomplish this, the “blame and shame” culture that permeates the existing regulatory and reporting cultures must be removed. Providers and others must feel confident that early reporting of an adverse event will not result in punishment. There would have to be a careful balancing of interests in this effort to assure that safe-harbors for reporting to not eliminate bona fide causes of action for patient medical negligence. The balancing of interests and the re-direction of regulatory sanctions in cases of no harm will require additional study.

A recent case before the Florida Board of Medicine provides valuable insight into the counter-productive character that voluntary reporting in the present system can produce. A surgeon was about to perform a procedure, but before doing so, realized that he was about to perform it on the wrong side. He caught himself, performed it properly and successfully on the correct side. A "near miss" report was made to the Board of Medicine. He was fined $10,000 and sanctioned by the Board.

Such disincentives to any kind of reporting must be removed and there must be a separate system in place for “near miss” reports that is entirely de-identified and not subject to sanctioning by the regulatory authorities. The PSC should conduct research to reduce the conflicts of interest between and among the regulatory entities (Boards of Medicine, Osteopathic Medicine, Nursing, Dentistry, Podiatry, Chiropractic) in
order to create a learning environment, rather than a punitive environment around patient safety. The construction of a “Near Miss” data and reporting system, which is a charge to the PSC, must include incentives to early reporting and assurances of de-identification.

The PSC should examine the merits of creating regulatory safe harbors for reporting. Appropriately balanced Safe Harbors should represent categories of activities for which no regulatory sanctions will be imposed if reported properly. For example the above case of a near miss wrong site procedure could be in a safe harbor category, exempt from punitive sanction – if timely reported by the practitioner involved. The PSC should examine the extent to which such safe harbors should also include any consideration in the event that recognized best practices/best outcomes/risk management strategies have been implemented by a provider. For example, if there are recognized strategies or procedures or systems that are known to improve patient safety and reduce medical error – and if these are shown to be in place, should there be any presumption with respect to liability, or should the presence of such systems be a factor that should be introduced as evidence of a good faith effort by the party alleged to have caused the harm, and liability reduced?

It was noted that the statutory teaching hospitals may have cultures and systems in place that encourage early reporting of incidents, thereby permitting these institutions to respond more quickly and often work out settlements with patients and/or families earlier. Shands and the University of Florida Self Insurance Plan have an excellent record of early reporting, early intervention and settlement.

The Workgroup recommends that there should be new provisions for the protection of pre-suit offers of settlement, thereby creating likely incentives to early settlement in meritorious cases. There are natural, built-in reactions to an incident among defense attorneys -- telling clients to say and do nothing, thereby reducing the likelihood of a just, efficient and early settlement due to fear that any discussions or offers would become part
of a record and prejudice the case. Early discussion that is protected may help to reduce the two year lag that is now common prior to many cases even being filed, and can encourage as well early reporting of incidents by providers. An early notice and protected discussion period may also provide a window of opportunity for variations of no-fault payments for limited, identified injuries.

Improvement in communication has been shown to be the single most important factor contributing to reducing preventable harm. It reduces both the likelihood of medical error in the first place at the front end, and substantially reduces the likelihood of litigation after an adverse event has occurred. While effective communication contributes to less litigation, the culture of shame and blame mitigates against this. If the regulatory system were able to focus on the evaluation of cases with a principle eye toward improvement of patient safety rather than punishing clinicians, this alone would help to change the culture.

The role of enterprise liability was also raised by the Workgroup. This involves health care institutions, principally hospitals, assuming the responsibility for insuring and absorbing the liability of individual practitioners. In Florida's current market where an increasing number of physicians are choosing to go “bare” – that is, not carry medical malpractice insurance, hospitals are being forced to make tough decisions about providing staff privileges to the physicians who generate the cases and produce the income. In addition, hospitals are struggling to determine how, if at all, they can afford liability protection to these physicians without overstepping the myriad federal and state fraud and abuse guidelines. While this may afford a degree of protection for injured parties and for physicians unable to afford the costs of malpractice coverage, it may place additional financial burdens upon health care institutions that should be studied and measured against the costs health care facilities may now experience if they permit doctors with no or inadequate coverage to practice. Presently, hospitals may be held disproportionately accountable for the negligent acts of uninsured or underinsured
physicians under vicarious liability theories, such as respondent superior, apparent agency, nondelegable duty, etc, or because of joint and several liability.

Incentives by malpractice insurance carriers to encourage safe practices by providers were discussed in several contexts. The Workgroup recommends that the PSC should compile evidence regarding programs such as the Colorado based medical liability insurance entity, COPIC, which has diversified insurance, brokerage and risk management products and services, and its effectiveness in reducing incidents and claims. This includes on-site risk assessments of physician offices and other practice settings for compliance with specific patient safety improvement provisions. Workgroup members recognize that other insurance lines, such as automobile, workers compensation and general casualty, include risk assessment programs that provide for reductions in premiums and/or other benefits to insureds who meet specific guidelines. Managed health care organizations currently include a variety of on-site risk management review, but it is not as comprehensive as it could be.

The PSC should examine the use of periodic payments, structured settlements, the creation of trusts, and other financial mechanisms that are intended to effectively and efficiently compensate persons who are injured. In doing this, the reasonable compensation for attorney services must not be compromised.

BEST OUTCOMES/ RISK MANAGEMENT STRATEGIES/ INCENTIVES

The creation of clinical protocols and guidelines for practice, particularly by government (such as the Centers for Medicare and Medicaid Services or the Agency for Healthcare Research and Quality) or third party entities (such as health insurance and managed care companies) and other players (such as employer coalitions and The Leapfrog Group) has been anathema to many members of the medical profession for decades. Often labeled "cookbook medicine," efforts to establish "best practices" or preferred procedures are viewed by many practitioners as dangerous because these guidelines tend to become standards rather than general parameters. At the same time, professional medical groups,
including medical specialty organizations, e.g., American College of Cardiology (ACC), have been developing and disseminating clinical practice guidelines, as methods for serving patient needs. Nevertheless, organizations like ACC recognize the limitations as well as the potential uses of clinical practice guidelines.

“Guidelines focus on the usual management of the average patient with a specific disorder and are not expected to be applicable to every patient because of the complexity of human biology and the fragmented nature of medical knowledge. Guidelines are used most effectively when the linkage to the underlying evidence is described, so that any necessary deviations from usual practice can be placed in proper context.” (ibid, p. 1133)

Government recommended or endorsed procedural guideline may also create an increased danger of litigation. If a government promulgated best practice has not been put in place or is not used by a provider, and there is an adverse outcome, there may be a presumption that the lack of the specific recommended procedure serves as evidence of negligence. Excessive and often inappropriate use of diagnostic testing or other medical procedures has been blamed on extreme defensive medicine – physicians performing excessive or unneeded diagnostic tests to avoid a later claim against them for not having done adequate testing.

But there is a substantive distinction between recommended guidelines (protocols, best practices) and best outcomes/risk management strategies. The goal of reducing medical malpractice litigation is directly associated with adverse outcomes. And the purpose of front-loading the health care system to reduce medical errors should focus on care outcomes, not just care process – otherwise, there is a risk that mere failure to deploy a specific process may be in and of itself a presumptive basis for liability. However, the Workgroup members recognize that there are important examples of clinical processes that have been demonstrated to unequivocally improve outcome, and that there are other instances of procedures, which while commonly used, have not been materially

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demonstrated to improve outcome. By focusing on outcomes, rather than process, clinicians and systems are afforded a window of flexibility in determining how to best achieve the best outcome.

Best outcomes should be studied by category of illness, disability, injury or disease. For each category, the kinds of adverse outcomes must be assessed, and the rates and characteristics of these must be subjected to rigorous epidemiological and root cause analyses. For example, misdiagnosis of breast cancer is one of the common categories of adverse outcome. A best outcomes goal would be to reduce the rate of misdiagnosis, if improved diagnosis would lead to improved outcome. Here, there is a subtle distinction between quality improvement – which could be a process measure, and improved clinical outcome. There are likely multiple procedural avenues that health care providers can implement to accomplish a targeted outcome. These may include a combination of institutional risk management strategies, communication system improvements, and certain clinical practices that are known to substantially improve the likelihood of correct diagnosis.

**The PSC should collect and maintain incidence and prevalence data about adverse outcomes, by disease, illness, disability and injury category.** These data should be based upon thorough analyses of closed claims and other data sources. The self-funded academic health centers in Florida (University of Miami, University of South Florida and University of Florida) have begun collaborating to share claims data knowledge and experience. The sharing of these data across other institutions will provide a basis for crafting expectations regarding best outcomes, identifying useful risk management strategies to achieve these outcomes, and creating incentives to the attainment of specific patient safety improvements in particular clinical areas. This will help to reduce the likelihood of malpractice litigation.
The Workgroup recommends that enhancing the underwriting process within medical malpractice insurers (both commercial and self funded) will contribute to the reduction of adverse outcomes and medical malpractice litigation.

Highly proactive hospital/enterprise underwriting committees are recommended to improve accountability, improve awareness and attitudes of clinical and administrative staff regarding types of risks, categories of adverse outcomes, and successful means by which to reduce risks. Encouraging independent underwriting committee activities – that is, external underwriting contractors rather than employed underwriters, has been shown at University of Florida and in other commercial insurance settings to improve objectivity and empower the committees to make useful recommendations.

Sharing data about outcomes, risks and root cause analyses with practitioners is not widely practiced by underwriting committees or by the institutions that have these data available. As a consequence, the dissemination of knowledge about what works, what does not, what can be avoided, and what can be embraced is not part of the gestalt within most health care settings.

The best outcomes approach includes an emphasis on determining how physicians make decisions about care. Distinguishing accountability from outcome is a delicate and important part of this process. For example, there is a difference between peer review and a morbidity and mortality conference.

Workgroup members endorse empowering practitioners by giving them data about themselves, relative performance with peers, and broader institutional, regional and national outcome expectations and realities. Many healthcare facilities do not share outcome data with practitioners, of they do, there is little effort to augment these data with education and follow up. Some practitioners, and many administrators and policymakers, can benefit from accessing the raw data in the system to conduct their own
comparative studies in order to better understand the characteristics of best outcomes as they may relate to improved patient safety processes.

The value of early reporting of adverse events is linked by the Workgroup with best outcomes and effective risk management strategies. Clinicians can benefit from improved awareness about statute of limitations issues, the importance of accurate clinical documentation, notice to risk managers upon awareness of the possibility of an adverse event, the advantages to settling prior to the filing of a formal complaint, and other procedural aspects of the post event litigation system.

**The PSC should assume a leadership role in encouraging the creation of educational programs for clinicians and the dissemination of relevant best outcome data and risk management processes to clinicians.** This could be accomplished by way of educational and training grants from federal entities such as the Health Resources and Services Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ) and private foundations, including foundations associated with major third parties and managed health care organizations doing business in Florida.

**Workgroup members caution about the PSC recommending and adopting statewide best practice or evidence based medicine practices in Florida.** Careful ranking of evidence and empirical information about the link between process and outcome is essential. There are substantive differences between the implementation and management of best outcomes and evidence based risk management strategies within hospitals versus within thousands of private practice settings and smaller clinics. Accurate, reliable data, based upon accepted scientific and statistical criteria and agreed upon parameters must be established with the consensus of the affected parties (clinicians in particular) before any government entity imposes them into the marketplace. As we note below, however, efforts are already under way within the private sector, through the Leapfrog Group[^4], various third parties, and the Centers for Medicare and Medicaid

Services (CMS) Quality Initiatives\(^5\), and the Agency for Healthcare Research and Quality (AHRQ) Quality Indicators and Patient Safety Indicators\(^6\), and Florida Agency for Health Care Administration’s efforts, such as its Nursing Home Guide\(^7\), to introduce exogenous measures of patient safety and best outcomes. As we note above, there is no dearth of public and private quality and patient safety indicators and guidelines. These should not be ignored.

Some Workgroup members re-stress their concern that any guidelines introduced may, in and of themselves, create liability and regulatory problems for providers because of presumptions about the relationship between such guidelines and good outcomes. Formally adopted guidelines are substantively different from textbooks or articles, because of what can become a presumption (at least by juries and the public) that they are formal endorsements of "approved methods".

**Workgroup members stress the importance of ensuring that any data and any reports issued by or through the PSC are accurate and credible.** There has been a plethora of data provided by various public and private sources, published in the media and by insurance companies that is discarded by providers due to low accuracy and credibility. The coordination of data acquisition, management and reporting by the PSC must be predicated upon commonly accepted data quality measures, and must be especially sensitive to the reception and use of these data by affected parties. Unreliable or poorly presented data may actually undermine the intention of the role of the PSC and its ability to improve safe patient outcomes.

**THIRD PARTY INCENTIVES**

A vital player in the assurance of safe patient care and medical error reduction is the third party organization --- health insurance and managed care companies. If frontloading the system is the best way to reduce adverse events that lead to medical malpractice

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litigation, then the organizations that are involved in structuring financial and clinical relationships must be actively involved in patient safety improvement.

This has been recognized in several, recent public and private sector efforts, including, but not limited to:

- The Center for Medicaid and Medicaid Services (CMS) Quality Initiatives, including the quality reimbursement program;\(^8\)
- Agency for Healthcare Research and Quality (AHRQ) Quality Indicators and Patient Safety Indicators;\(^9\)
- The Leapfrog Group, patient safety and quality outcome programs;\(^10\)
- "Pay for performance" programs within various public and private sector third party and provider networks.

**The PSC should encourage active, direct involvement of third party insurers and managed care companies in the development of programs that create incentives for physicians and hospitals to improve patient safety and reduce medical errors.**

The Centers for Medicaid and Medicaid Services has initiated a three year demonstration project to reward a sample of hospital participants for measured quality performance in five categories of care: heart disease, pneumonia, coronary bypass graft, hip and knee replacements.

Thirty four separate quality measures associated with demonstrated improved patient safety, reduced errors and improved outcomes for these categories of illness or disease, are being measured in 278 hospitals across the nation. Through its Medicare reimbursement system, CMS will award increased reimbursement for hospitals that demonstrate higher performance in these measures. Hospitals ranking in the top 20% of the group will receive an additional 1% Medicare bonus; hospitals in the top 10% for a specific diagnosis will receive a 2% Medicare bonus payment.

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The federal Agency for Healthcare Research and Quality (AHRQ) is the health services research component of the U.S. Department of Health and Social Services. AHRQ has implemented a federal initiative to derive data from hospital records regarding quality and tracking over time. To accomplish this, a set of quality indicators has been developed from years of research and testing. These indicators consist of prevention measures, intended to identify hospital admissions that could have been avoided by better quality outpatient care, and inpatient measures, reflective of quality of care.

The AHRQ initiative is intended to provide health care institutions and practitioners with accurate and reliable measurement tools for studying aspects of patient safety improvement by medical condition, procedures, site and volume. The AHRQ efforts are intended to encourage the most appropriate use of effective health services providers and to provide consumers with easily accessible data about the safety and quality of health care provided in their communities. Evaluating the impact of AHRQ's data and reporting efforts on patient and provider outcomes will take several years of testing and implementation, but their early use is sensitizing health care institutions, providers and consumers about the importance of surveillance, monitoring, tracking and trending valid measures of patient safety in order to reduce medical errors.

The Leapfrog Group is a privately funded initiative, composed of 150 public and private organizations providing health care benefits. The Leapfrog Group has developed incentive and reward programs designed to leverage corporate employers to demand more of their providers and third parties. It does this by getting large payors to agree to purchase health care services from providers who meet Leapfrog patient safety and quality outcome standards. These standards are related in some respects to AHRQ initiatives, but include other measures and standards that must be met by participating providers if they are to receive the Leapfrog imprimatur.

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Commercial health insurers and managed health care organizations have begun to speak to and give financial support to encouraging health care providers they pay to adopt error reduction and quality outcome measures to improve patient safety. Some of the most successful early efforts among commercial third parties to influence care outcome were implemented in the early 1980s by Sam Kaplan’s U.S. Administrators, a California based third party administration company that used claims and supporting medical data to establish standards of care and outcome – and to impose reimbursement differentials based upon performance. Florida had an early and successful quality of care system that was linked to cost containment in the mid to late 1980s: Joe Charles and Ryder Systems, based in Miami, had a nationwide data system it used to monitor certain outcomes and costs, and to negotiate reimbursement contracts with providers all over the nation.

Pay for Performance is a generic category of incentives that are being developed and deployed across the nation through various third party and employer sponsored groups. It is based, in concept, on the CMS differential reimbursement model, and establishes quality and patient safety outcome goals that are measured periodically within and across providers (hospitals and clinicians). Success in achieving goals by providers is rewarded with differential payments or bonuses. Failure to meet goals may subject the provider to reduced payment – or even removal from a list of preferred providers.

Pay for Performance consists of incentive systems tied to the provision of high quality care. Currently, a small proportion of health insurers report performance results through fully implemented quality incentive programs. Many more plans are developing and refining systems to provide financial and other incentives to physicians and hospitals for improving clinical processes and outcomes. Five categories of financial incentives are used by purchasers in pay-for-performance systems:

- Bonus Payments
- Improvement Projects
- Performance Fee Schedules
- At-Risk Contracting; and
- Consumer Cost Differentials
Bonus payments are made to high-performing providers for meeting goals based on measures such as patient satisfaction, service utilization and clinical results. Providers may receive incentives for implementing projects that can be shown to improve quality. Differential fee schedules may be developed that compare physicians to national standards based on performance. Performance may be considered during contract negotiations, where a portion of annual payment increases are based upon a specified level of performance.

The largest initiative launched by the Integrated Healthcare Association (IHA) in 2002 in California utilizes a public scorecard in which rewards are based on clinical measures (six Health Plan Employer Data and Information Set (HEDIS®) measures at 50% weight), patient experience (the California Cooperative Healthcare Reporting Initiative, CCHRI, consumer Assessment Survey at 40% weight) and information technology (two domains: clinical dataset integration and clinical decision support at 10% weight). While IHA targeted incentive payments at 5% to 10% of physicians’ capitation payments, each plan individually decides the source, amount and payment method. For example, Independent Health in upstate New York makes incentive payments of up to $2.00 per member per month to high-performing physicians participating in the program.

Physician’s Direct of Oklahoma, in partnership with HealthGate Data Corporation, is launching the ePPO health care delivery model. HealthGate’s software program includes an interactive “decision tree” based on a set of evidence-based guidelines for over 117 illness and conditions that have been developed by an academic consortium that includes: Duke University Medical Center, Emory University Health Sciences Center, Oregon Health Sciences University and Vanderbilt University. Doctors in the program will receive higher reimbursement, and patients will be offered a consumer-friendly version of the guidelines, as well as points to reduce co-payments, for participating on on-line tutorials to demonstrate understanding and compliance.
Florida and other states have sought to produce consumer data about hospitals and physicians. These "report card" efforts have involved substantial efforts in various states, but as reported in the Section 35 and 36 reports, the use of these systems by consumers has been low, and the credibility of the data used to produce the report cards has been subject to challenge. Recently, in Florida, there have been very well publicized efforts to produce reports about nosocomial infections within hospitals, and other select adverse events.

**CONCLUSION**

In the Section 36 Report, the Academic Task Force on Patient Safety concluded that:

> Successful litigation alternative systems and policies would reasonably be expected to lower professional liability premiums, increase availability of insurance, while providing greater incentives for physicians of all specialties to select Florida as a state of choice in which to establish and maintain a medical practice. (Section 36 Report, P. 285)

Good science and evidence-based medicine do not consistently serve as the basis for what constitutes patient safety within Florida's medical malpractice litigation system. Rather, anecdotal presentations by experts and presumed, but unproven patient safety enhancement and error reduction strategies litter the landscape. Most errors are system failures – not the fault of individuals. Yet a culture of blame has been allowed to fester upon our nation's health care system and its providers, and it has infected that system, producing antibodies against patient safety improvement and error reduction. We have not taken a patient centered approach to improving safety. All of these factors have created a liability, litigation and a patient safety crisis. It is time for a change. (ibid. p. 291)

It is time for a change, and this Workgroup has taken an important step by bringing together most of the vested interests that are designated to serve on the Board and Advisory Committees of the newly created Florida Patient Safety Corporation. The dialogue and growing trust that have evolved among the individuals has established a realistic basis for making Florida the poster state for patient safety improvement coupled with sensible medical malpractice reform.

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