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The Challenge of the Shrinking Market and the Role of Tort Reform

Physician Insurer

P IAA members and the admitted medical professional liability (MPL) industry at large are facing a growing challenge, as physicians exit private practice and become employed by hospitals and health systems that provide them with MPL insurance coverage. Most of this coverage is through hospital-owned captives or self-insurance plans. Over the past decade, issues relating to the shift in physician practice expectations and lifestyle have been discussed at PIAA meetings, and indeed, these forces are now coming into full play, as evidenced in our marketplace.

For example, in 2005, 23% of the physician search assignments conducted by national physician search and consulting firm Merritt Hawkins featured hospital employment of the physician. That number grew to 45% in 2009. A recent New York Times article by Gardiner Harris reported that more younger physicians are deciding against private practice, in deference to the regular hours and financial security of employed practice. This also impacts older physicians, who are finding it harder to recruit junior partners, and instead sell their practices and become salaried as well. While the Times opines that bigger organizations may be able to provide better, more coordinated care, it fears that “the intimacy of longstanding doctor-patient relationships may be going the way of the house call.”

An American Hospital Association 2010 survey of 572 community hospital CEOs revealed that 65% of those who responded are making efforts to increase the number of employed physicians overall, and 80% are trying to increase the number of employed primary care physicians. This is clear evidence that the trend PIAA members have seen emerging will continue and probably intensify.

And, there is good reason why hospitals want to increase the number of employed physicians. A recent Merritt Hawkins survey of hospital CFOs showed that, while the average salary paid to a family medicine physician was $173,000, the average revenue generated for the hospital was $1.6 million. By comparison, neurosurgeons had an average annual salary of $571,000, and generated hospital revenues of $2.8 million.

The PIAA is at the core of trying to alleviate one of the forces driving physicians away from private practice—the expense and emotional strain of defending against accusations of medical negligence. Our 25 years of experience with the PIAA Data Sharing Project clearly demonstrates that more than 70% of claims and lawsuits brought against physicians are without merit and resolved in favor of the physicians. However, as we all know, the price of victory (if you can call it that) is high, involving years of litigation and the frustrations and distractions it entails.

As I write this, the tide for tort reform in Washington is beginning to turn for the better, and we are preparing for a hearing on MPL reform in the House Committee on the Judiciary. We also expect the reintroduction of H.R. 5, the HEALTH Act, in coming weeks, and the debate to continue. As we all know, our industry is financially stable at present; however, for those states that do not have effective tort reforms, nothing has really changed over the past 30 years to limit lawsuit abuse. It’s undoubtedly a steep hill to climb, and we will look to our members for grassroots and lobbying support to move the ball forward. This year, 2011, will be an important one for this effort. Given the makeup of the U.S. Senate, it is not likely that a bill will be passed in that chamber; however, each time legislation has been considered in the past several years, there is increasing acceptance of its necessity. If we keep at it, we’ll get there.
It is important to note that the largest claims are not necessarily getting larger. Rather, it is the severity of the medium, or “typical” claim that is growing.

—Cover story
As much as it embarrasses me to admit it, it’s true—Valentine’s Day is my favorite holiday! I suspect this admission may surprise those of you who know me, as well as those who don’t know me personally but do know, or have at least heard stories about, actuaries. Like most of my fellow left-brain thinkers, I need to plan out in great detail, and well in advance, how to act spontaneously—say, for example, by purchasing a card, a box of chocolates, or some other gift (new regression software would be nice, in case anyone is taking notes) for a significant other.

And thus, every year, as the 14th day of the second month approaches, I, and many others like me, revel in the notion that we, too, can be creative, thoughtful, and, dare I say, even sensitive, all on our own—at least when we are coerced and basically forced to because of unfair and illogical social pressures, unchallenged and irrelevant national traditions, Hallmark and Godiva Chocolatier advertising campaigns, etc., etc.

Of course, in addition to the shallow, commercially driven giving of the holiday, the other thing that the 14th day of the second month also brings into focus is this: there are only 14 days remaining to estimate, develop, allocate, and record that most lovely of accruals on insurance companies’ balance sheets, that being, IBNR. Christmas has 12 days, Labor Day is a mere weekend long, and Festivus is limited to a single day. But the season of Valentine carries on for two full weeks, with an extra day thrown in every four years—surely a reflection of its importance, since no other holiday can claim this special treatment. It is during this precious time of year that, if you listen closely, you might just hear this familiar tune echoing through the corridors of the finance departments at PIAA member companies:

On the first day of Valentine, our CFO told me, Send data to the actuary.

On the second day of Valentine, our CFO asked me, Why don’t we have results yet.

On the third day of Valentine, our actuary began, Selecting loss development factors.

On the fourth day of Valentine, our actuary added, A hindsight outstanding method.

On the fifth day of Valentine, Marketing declared, We love I-B-N-R. …

The Valentine season reaches its crescendo with the March 1 filing deadline for PIAA member companies’ statutory annual statements. The results that have been encapsulated in these statements during the past few years are certainly something to admire, and it is my expectation that the message contained in this season’s results will continue this recent trend of good news.

While these risks, which can range from tooth decay to diabetes, may take several years to manifest themselves, they are nonetheless present, and should be monitored. PIAA member companies should also be cognizant of the longer-term risks that can eventually develop, on the heels of the sweet results of late. Care should be exercised, so the effects of the slow, but sure, erosion in the average collected rate levels over the past several years do not result in decay in the companies’ results, to the point where a financial cavity develops, or worse yet, a more serious and chronic financial condition—the MPL equivalent of a root canal.

Fortunately, most PIAA member companies find themselves in possibly the best financial shape of their existence, and so their job is to maintain their status, rather than the more difficult task of trying to remedy it. One of the more effective exercises a PIAA member company can undertake in this regard is to review the actuarially indicated ultimate loss ratios for each separate business segment, and compare those indications by incurred year, to look for trends over the past several years. In addition, a review of changes in the indicated loss ratios, since the previous analysis, can be instructive in identifying the early onset of possible deterioration in results.

With the joyous Valentine season once again upon us, let us all celebrate how fortunate we are to be able to focus our affection on our statutory sweetheart—IBNR.

Chad C. Karls, FCAS, MAAA, is a Principal and Consulting Actuary at Milliman, Milwaukee.

BY CHAD C. KARLS

The Fourteen Days of Valentine

I IBNR

Chad C. Karls, FCAS, MAAA, is a Principal and Consulting Actuary at Milliman, Milwaukee.
Obviously inevitable, the Patient Protection and Affordable Care Act has opened a new frontier in American education. An entity that refers to itself rather sweepingly as the “American College” is now offering the Chartered Healthcare Consultant™. The curriculum comprises five core courses, and one elective. The information gained will, the American College claims, “open doors with both employers and individual clients.”

Your course of study will include:
- Mandated changes and immediate adjustments to social programs
- The terms and definitions you will need to know to operate in the new environment
- Programs and incentives offered by the government
- State exchanges and the “navigator” role
- Internal and external review processes
- Impacts to HIPAA, ERISA, and the CLASS Act.

What will happen to the course content, to say nothing of the chartered designation, in the event of the Republican-led repeal of the PPACA, is not specified.

Source: The American College, December 30, 2010

The Crystal Ball on Hard/Soft Market….Finally Clear?
New prediction shows robust self-confidence

Every week, it seems, one can read that the soft market for property/casualty insurance is finally on the upswing. Estimates as to the timing, however, differ widely, and the certainty of the language varies nearly as much. But now, the chief executive from MarketScout, Richard Kerr, has come down from the mountain (it’s in Dallas, so we’re not talking about major declivity here) to announce that prices will commence an upward swing in the second half of this year.

He noted that although rates did decline last year, there was some moderation in pricing, and they held relatively steady within a narrow range, of 3% to 5%.

Kerr has prognosticated, “2010 will prove to be the beginning of the end of a six-year soft market cycle.” He thinks that the first six months of this year will see slight reductions on “competitive-ly marketed placements” and flat renewals on markets not under those pressures.

“By year-end 2011, the longest soft market period in the last 70 years will finally come to a close,” he declared. “For those who have been asking for just ‘one more hard market,’ your time is coming. You have six to nine months to get ready. Be prepared. Those with the ability to rapidly deploy products will win big.”

Source: National Underwriter, January 6, 2011

Another Top Ten List: Technology Hazards

According to PIAA affiliate member the ECRI Institute, technology-related adverse events are largely preventable, but they need to be “clearly understood and thoughtfully acted upon.” In a new report, ECRI cites ten technologies that may be particularly vulnerable to errors. The text provides ample coverage of the diverse sources of these hazards, and lots of wise counsel on how to prevent them.

1. Radiation overdose and other dose errors during radia-

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PHYSICIAN INSURER  F I R S T  Q U A R T E R  2 0 1 1
when the doctor who was being sued treated an ill juror, in the courtroom in front of the other jurors—the MPL lawsuit ended in a mistrial. The Jonesboro, Arkansas, Sun reports that the juror became ill during the opening statements of the lawsuit against Dr. Stephen Eichert. The juror’s name and specific condition have not been disclosed.

Eichert is being sued by Cristina Renee Chaffin for allegedly not performing the proper tests before operating on Chaffin’s back and failing to tell Chaffin of the risk of surgery. She is asking for $75,000 for the cost of two surgeries and follow-up visits and lost wages, plus an amount to be determined for pain, suffering, and mental and emotional anguish.

It was Chaffin’s attorney who asked for the mistrial, and Eichert’s attorney, not surprisingly, agreed.

Source: Associated Press, December 21, 2010

Checklists Could Prevent Nearly One-Third of Surgical Adverse Events

The SURgical Patient Safety System (SURPASS) checklist covers the complete surgical pathway, from admission to discharge. A new study from Holland used MPL claims to assess the proportion and nature of claims that might have been prevented if the SURPASS checklist had been used. The database comprised 224 settled closed claims for incidents that occurred between January 1, 2004 and December 31, 2005. Data on the type and outcome of each incident and its contributing factors were extracted. All contributing factors were compared to the SURPASS checklist to assess which incidents the checklist might have prevented.

Failure to diagnose and peri-operative damage were the most common categories of incidents, while cognitive contributing factors were present in two-thirds of claims. Of 412 contributing factors, 29% might have been intercepted by the SURPASS checklist. The checklist might have prevented 40% of deaths and 29% of incidents leading to permanent damage.

The authors conclude, “A considerable amount of damage, both physical and financial, is likely to be prevented by using the SURPASS checklist.”


ER Patients at Risk Because of Lack of Specialists

Mental patients stay in ER for days

Nearly three-quarters of hospital emergency administrators nationwide say that a scarcity of medical specialists at their facilities poses a risk to patients—and in some cases, a very significant risk. They are also worried that the new health reform law will cause additional ER crowding and that mental health services in particular will become increasingly inadequate.

A new survey done by the Schumacher Group, an ER management firm, took stock of staffing and operational trends at more than 600 hospitals nationwide. They say that the lack of other specialists, such as orthopedic surgeons, neurosurgeons, and even general surgeons poses a moderate risk to patients, and nearly 40% indicated that shortages of specialists poses a “significant” or a “very significant” risk to ER patients.

“There is a ‘golden hour’ after patients undergo trauma or severe illness when it is crucial that they receive specialty care,” says William Schumacher, MD, CEO of Schumacher Group. “When specialists are not able to provide care, patients must be transferred, and the critical hours may be lost.”

Eighty-six percent of hospital ER administrators said that their facilities are sometimes or often unable to transfer mental health patients to inpatient facilities in a timely manner. Because of the shortage of beds at inpatient facilities, many mental health patients must be boarded at the ER for days at a time. Some administrators have said that their facilities have experienced boarding times for mental health patients of one week or more. Sixty percent said patient care at their facilities is definitely compromised as a result of long boarding times for these patients.

Source: PR Newswire, December 17, 2010

Source: ECRI Institute, Health Hazards, November 2010
From the PIAA Chair

Why PIAA Membership Matters

Perhaps second only to the medical insurance crisis that led to the creation of so many PIAA companies in the 1970s, the burdens and challenges for physicians today are significant and growing: electronic health records, hospital purchases of physician practices, a vast influx of patients expected from healthcare reform, and an aging Boomer generation.

So it is hardly surprising that our physician-run organizations would have their own share of challenges, including new CMS reporting requirements, state-by-state attacks on tort reform, shifting standard of care definitions, and company consolidations. Never has membership in PIAA been more important.

On medical professional liability laws, your organization is actively reminding federal lawmakers that meaningful tort reform not only increases Americans’ access to care, it also can have a significant impact on the federal deficit. That conversation is becoming increasingly bipartisan, and with the recent historic Congressional elections providing the PIAA with a new—and very likely receptive—audience, we will keep that message burning brightly throughout 2011.

James L. Weidner is Chief Executive Officer of the Cooperative of American Physicians, Inc. and Chair of the PIAA Board of Directors.

But PIAA needs your help to bring that message home. By allowing the PIAA Political Action Committee to solicit contributions from your executive staff and board members and by your company’s direct support to the PIAA PAC, we will be a factor in 2012. If you think your doctors expect anything less, just ask them.

At the same time, we want to develop effective new tools to help our companies defend doctors who face medical professional liability litigation. In 2011, an advisory group of PIAA members will analyze software, vendors, and key features for the implementation of an Internet-based expert witness database. Such a tool will go a long way toward catching those who would offer junk science in the courtroom instead of helping to find the truth.

Of course, it is the task of all our companies to help physicians avoid patient injuries altogether. That is why the PIAA is a participant in iHealth Alliance, a not-for-profit organization of medical societies and medical professional liability companies. More than a dozen PIAA member companies participate in iHealth Alliance, and we are excited about the strides it will make in patient safety and risk mitigation in 2011.

Also promising fresh contributions to safer medical practice is the PIAA Data Sharing Project. The Data Sharing Advisory Committee this year has a new chair, Scott Diener of NORCAL, and we look forward to Scott’s leadership as the committee works to enhance the data sharing project and its research agenda.

The delivery of high-quality education will remain a key initiative of the association in 2011, and I encourage all members to take advantage of our unique and unmatched educational offerings. No other educational options available to MPL professionals can provide the depth of information, quality of speakers, and unparalleled networking opportunities as those provided by the PIAA. This year will also see the unveiling of the reengineered Annual Meeting—now called the PIAA Medical Liability Conference. Be a part of this “can’t miss” event, as the PIAA takes center stage in Scottsdale, Arizona, in May.

As we move closer to the year’s biggest single PIAA event, your Board of Directors is also pleased to report that significant progress is being made to identify a new president. Larry Smarr’s retirement from the PIAA in May after 19 years will mark the end of an era of remarkable progress for the Association. We thank Larry for his stellar contributions and have no doubt that Larry’s successor will build on his achievements while finding new ways for the Association to serve the MPL market.

As for our industry itself, all signs point to a continued soft market in 2011. This factor, along with the continued exodus of solo practitioners and small physician groups (a key client base for PIAA carriers), will likely lead to another year of decreased premiums. These lower premiums are great news for our physicians, but they put pressure on PIAA membership dues—the financial underpinning of the Association. The PIAA operates as a nimble, cost-conscious organization. We watch the budget closely and make every effort to stretch your dues dollars. Your continued support and commitment are key to delivering all of the benefits that I have noted here—and many more.

So I ask that you consider these factors as you assess your support of the PIAA in 2011. Come to our meetings and workshops, visit our website, and take advantage of all of the other resources that the PIAA offers you. The PIAA is truly a key element of the physician and other provider-directed MPL community—so let’s work together to make 2011 the best ever for those who so heavily depend on us.
The PIAA Annual Meeting has a new name—
and a new focus!

Make plans now to attend the

2011 PIAA
Medical Liability
Conference

May 11-14 • Westin Kierland Resort • Scottsdale, Arizona

The 2011 PIAA Medical Liability Conference will be the year’s most important event. This conference, formerly known as the Annual Meeting, has been renamed to reflect the PIAA’s new vision for this annual event, and its more focused content.

The 2011 PIAA Medical Liability Conference features:

- High profile speakers, including Joseph J. Plumeri, Chairman and CEO, Willis Group Holdings plc
- More concurrent sessions! Topics include:
  - The diminishing pool of solo-practitioners and small physician groups
  - Formulating an effective defense in multi-defendant cases
  - ACOs—what are they and how will they impact MPL?
  - Transfer of care—avoiding MPL claims
  - MPL insurers and electronic data
  - And many more!

If you attend one insurance industry meeting in 2011, make it this one!

Register today!

For detailed information about the conference, or to register, go to www.piaa.us

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Message Orchestration: Creating a Harmonious Communications Program

During our country’s recent and widely publicized economic downturn, many businesses were forced into survival mode. Some were compelled to cut budgets, change philosophies, or even scale back on staff, possibly terminating entire departments. These steps, while necessary, drastically changed how some companies did business. But now, as we move into 2011 with a refreshed outlook and are seeing positive signs for a strong future, businesses can begin to reevaluate what has been going on and make sure they are poised for growth.

Eric M. Morgenstern, APR, Fellow PRSA, is president and CEO, Morningstar Communications, Overland Park, Kansas. Mr. Morgenstern will be speaking at the upcoming PIAA Marketing Workshop, April 6-8, 2011, Scottsdale, Arizona.

In short, businesses are transitioning from survival mode to growth mode. Each area of your organization has an opportunity to regain perspective and blend together as a cohesive unit, creating a comprehensive program to engage all audiences, including employees, current customers, and prospects. Take the time to clearly identify your organization’s audiences, and create appropriate and consistent messages that resonate with each—this is a process I call “message orchestration.”

Get in tune
Imagine your business as a symphony orchestra where each department represents a different instrument section. The goal is to take every instrument, of varying sound and purpose, and make them come together to perform a beautifully orchestrated piece. That cannot be done if everyone plays in a different key. If each section is working from a different score, the sound will be jumbled, useless, and out of tune.

The same thing can be said about a company working on engaging customers, growing the business, and telling a story when everyone (that’s everyone) is not on the same page. With so many companies fully embracing the concept of the customer experience, it might be time to regroup and make sure every piece of the organizational symphony is aware of the company’s message and how it should be orchestrated.

Message orchestration transcends traditional integrated marketing communications and instead adopts a more all-encompassing philosophy, which is practiced throughout the company—from intern to CEO. This means organizational messages, practices, policies, and overall look-and-feel need to be adhered to, no matter where it is within the company.

For example, the booth that HR has set up at a job fair needs to be armed with the company’s messages and look like the website the recruit will visit to research the company. Sales and customer service will work together and articulate the same messages and policies as HR. Meanwhile, your social media, marketing, and communications departments will be using the same messages to attract the external customer. This steadfast consistency creates an environment in which all of the pieces are work-

Continued on page 10
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Continued from page 8

ing together, and the individuals in your
internal audience can clearly see the goals
of the company and understand their role
in meeting those goals.

The idea of having a unified message
is not new; it’s the basis of any integrated
marketing communications program.
The company’s message must be clear
and consistent at every turn, including on
the website, in RFP responses, in face-to-
face client interaction, etc. However,
sometimes the message is only relayed
internally with a “there it is, do what you
can to implement it in your department,”
and no further direction.

This is the equivalent of a symphony
attempting to play Beethoven’s 5th without
any instruction or rehearsal. Instead, the
message can be controlled and delivered
so every person knows precisely what is
expected of him or her, how it fits into the
overarching goal, and what the anticipated
benefit will be. By systematically infusing
the message throughout the entire organi-
zation, we can ensure the overarching
messages and goals are absorbed and acted
on, consistently and appropriately. Message
orchestration makes it possible to include
every potential touch point to create brand
advocates out of both internal and external
audiences.

Find the right note
The message itself is supremely impor-
tant in this process and should not be
hastily scribbled down and disseminated.
It will be best received if it meets the
three principles of effective messaging.
First, keep the message simple. Clearly
state what is expected of each individual
involved and the resulting outcomes. This
will ensure each person, in every depart-
ment, will have a clear understanding of
how he fits into the overall program.

Second, the message must be recipient-
oriented. It should not be thought of
in terms of what you want to tell, but
rather what the recipient needs to hear.
Sure, a trumpet player wants to know
what is going on with other musicians
involved in the piece, but it’s his specific
role that is most critical to him. Targeted
messages mean that everyone gets the
exact information he truly needs.

Finally, the message must be easily
articulated. As with music, a complex
piece still needs to be easy to understand.

Play your song
Once the audience-specific messages are
understood, and each individual knows
the role he plays and how it fits into the
overall program, implementation can
begin. This does not mean, however, that
everyone is on his own. Just as a conduc-
tor ensures each section is working
together for the perfect blend, company
executives must remain engaged and see
that each person, at every touch point, is
telling your story and playing his part
accurately, effectively, and consistently.

While it would be great to just sit
back and enjoy the music, for the conduc-
tors of business, it takes proactive orches-
tration and wholesale internal buy-in to
translate your message into something
clear, useful, and harmonious. The cur-
tain is rising on a brand-new business
environment. Is your company ready
and deserving of a standing
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to recover on a claim of malpractice: (1) a duty of the psychiatrist to provide professional services within the prevailing standard of care; (2) a breach of this duty; (3) which caused; (4) injury to the patient. The issues of whether the psychiatrist’s diagnosis or treatment fell beneath the standard of care in rendering professional services and whether such alleged acts or omissions caused or directly resulted in the patient’s suicide are usually the subject of conflicting expert testimony. However, the issue of whether the physician owes a professional duty to the patient in the first instance is usually a decision to be made by the courts as a matter of law. Many states clearly recognize the duty of a psychiatrist to provide professional services in a manner so as to prevent or minimize the risk of suicide in a hospitalized patient. Whether a similar duty exists when the patient is being treated on an outpatient basis remains an unsettled question in many states. Several courts have recently addressed this largely unresolved issue.

McKnight case and “unconditional” outpatients

In McKnight v. South Carolina Department of Corrections, the Court of Appeals of South Carolina found that the duty of care owed to the patient ceased upon his discharge from the hospital. In McKnight, the patient denied wanting to commit suicide but admitted that he was depressed and had a long history of suicidal ideations or threats of harm, prematurely discharging a patient, or failing to confine a known suicidal patient.

In virtually every jurisdiction, the plaintiff must prove the four essential elements of professional negligence in order...
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Continued from page 12

ical examination, prepare an appropriate treatment plan, medically manage the patient, prepare an appropriate discharge plan, and provide appropriate follow-up treatment, which caused or contributed to the patient committing suicide.

The court recognized that the psychiatrist’s duty extended to a patient who is confined to the hospital, but found that this duty does not continue once the patient is discharged and can no longer be supervised and monitored by the physician. The court emphasized the psychiatrist’s lack of control over an outpatient as reason not to impose a duty to prevent suicide in the outpatient context, but opined that a healthcare provider may still be liable if a patient has not been “unconditionally” released, for example, when a patient is outside of the hospital on a hospital or physician sanctioned temporary outing.

The McKnight case suggests that in jurisdictions where physicians cannot normally be held liable for the suicide of an outpatient, it may still be a risky proposition to voluntarily allow patients to leave the hospital on day passes, overnight passes, or other outings if the patient has not been discharged from inpatient care.

Duty and the physician-patient relationship

In Estate of Eric S. Harr v. Ulwelling, MD, the New Mexico Court of Appeals determined that the duty to prevent a patient’s suicide requires that the psychiatrist have the ability to exercise control over the patient’s treatment and the psychiatrist must have an ongoing physician-patient relationship with the patient.

In Harr, the patient failed to return for scheduled appointments after three months’ treatment with the defendant psychiatrist. The patient later admitted himself for inpatient treatment by a different psychiatrist, without consulting the defendant, and attended outpatient treatment sessions with a different provider before returning for counseling by a psychologist employed by the defendant. After three sessions with the psychologist, the patient failed to return and committed suicide three weeks later.

The patient’s estate sued the defendant psychiatrist for malpractice leading to the patient’s suicide. The court determined that because the decedent had not been treated by the defendant psychiatrist for several weeks before his death, the intervening inpatient psychiatrist had not communicated with the defendant, and
the defendant had not been provided a copy of the decedent’s inpatient discharge summary, the physician-patient relationship between the defendant and the decedent had been effectively terminated by the decedent’s actions prior to his suicide.

Turning to the issue of duty, the court stated that when a patient is hospitalized, the physician is both responsible for, and has the ability to administer, most aspects of the patient’s treatment. By contrast, outpatient physicians have responsibility for most of their own needs, and the healthcare provider has only a limited opportunity to supervise them. The court therefore concluded that even if the physician-patient relationship had survived, imposing a duty on the psychiatrist to control the actions of an outpatient would be unreasonable and practically unworkable.

The Haar opinion underscores the importance of physician-patient communication and documenting the extent of interaction between the psychiatrist and patient.

**Duty to prevent “foreseeable” suicides**

Other courts have found that a determination of whether a psychiatrist has a duty to attempt to prevent the suicide of an outpatient turns upon whether the suicide is reasonably foreseeable.

In the Florida case of Lawlor v. Orlando, the patient was being treated for depression on an outpatient basis at the time of his suicide. The testimony of the defendant, the decedent’s wife, and other fact witnesses indicated that while the decedent exhibited depression, he had not exhibited suicidal ideation or made threats of suicide, and a suicide screening conducted a few months prior to his suicide did not reveal a specific risk of suicide. The only testimony that the suicide had been foreseeable was that of the plaintiff’s expert. On these facts, the court concluded that the suicide was not foreseeable, and therefore no duty existed on the part of the defendant to prevent it.

In the case of Patton v. Thompson, the plaintiff alleged that the patient was prematurely discharged after an attempt to prevent suicide and that the psychiatrist did not prepare a proper outpatient treatment plan, and both factors were causative in the patient’s suicide. On these facts, the Supreme Court of Alabama found that a psychiatrist has a duty to guard against the suicide of an outpatient when the patient’s prior behavior or statements would lead a healthcare provider to reasonably foresee that the patient may commit suicide. The Patton court set forth three factors to be considered in determining whether a suicide is reasonably foreseeable: a history of suicidal proclivities, manifestations of suicidal ideations or statements in the presence of the provider, and previous treatment by the provider resulting from a suicide attempt.

The foreseeability factors set forth in Lawlor and Patton illustrate that foreseeability is a fact-based determination and that analysis of duty in such cases will often turn on the testimony in the case. For example, it remains unsettled whether a duty will be imposed on a psychiatrist when a patient, admitted for short-term detoxification after an apparent overdose, is discharged for outpatient treatment and then unexpectedly commits suicide.

**Duty to involuntarily hospitalize patients**

The Lawlor and Patton cases also raise the question as to whether the physician has a duty to involuntarily hospitalize a patient who is a known suicide risk.

Some courts have answered this question and have held that psychiatrists cannot be held liable for failure to involuntarily confine an outpatient. Paddock v. Chacko, MD, offers one example. Acknowledging that Florida has a statutory process for involuntarily committing a patient for psychiatric treatment, the Paddock court noted that the terms of Florida’s statute are permissive rather than mandatory, and the decision on whether to involuntarily confine a patient is left to the professional discretion of the psychiatrist. The Paddock court recognized that “[t]he science of psychiatry represents the penultimate grey area”... and that “[n]umerous cases underscore the inability of psychiatric experts to predict, with any degree of precision, an individual’s propensity to do violence to himself or others.”

**Conclusion**

In general, courts have found that psychiatrists have a professional duty to attempt to prevent an inpatient’s suicide. However, the extent of a psychiatrist’s duty to attempt to prevent the suicide of outpatients remains an unsettled issue in many jurisdictions. The court opinions issued to date indicate that while many courts are hesitant to impose such a duty in the outpatient setting due to lack of control over the patient, the element of foreseeability is often the controlling issue. In light of the inherent fact-based variability in whether a suicide was reasonably foreseeable, the question of a psychiatrist’s duty to prevent the suicide of an outpatient is expected to continue to remain a much-litigated issue in such lawsuits. For related information, see www.conroyseimberg.com.

**References**

Sweeping change seems to be the rule, rather than the exception, when it comes to federal elections in recent years. At the start of the 111th Congress (2009-2010), there were legitimate concerns about not only Congressional antagonism toward medical professional liability (MPL) reform, but also about the very real possibility that legislation harmful to the MPL insurance industry would be enacted. In the end, though, we avoided new federal regulation of the MPL insurance industry, saw bipartisan calls for effective MPL reforms (although none were enacted), and defeated efforts to repeal the limited antitrust exemption for MPL insurers.

But now, as the new Congress begins, there is substantially more reason for optimism than we have had for several years. There is a new Congressional tort reform caucus (tentatively called the Civil Justice Reform Caucus) in development that will educate fellow Members of Congress about the issues surrounding tort reform. Early meetings with the Caucus’ bipartisan leaders have been fruitful, and we will continue to work with the Caucus to inform Members of Congress about the role of tort reform in the MPL insurance industry.

The new leaders of the House of Representatives, meanwhile, are even more specific about the need for reform. Their “Pledge to America,” drafted as a campaign platform in 2010, unambiguously states that the new Congress will enact real MPL reforms as part of the effort to address healthcare issues—an explicit reproach to the pseudo-reform included in the healthcare reform bill passed by the previous Congress.

Specifically, the Pledge states, “We will enact common-sense medical liability reforms to lower costs, rein in junk lawsuits, and curb defensive medicine.” As the 112th Congress kicks off, it is clear that the leadership is committed to following up on this promise.

Before the 112th Congress even began, Congressman Phil Gingrey, MD (R-GA), the champion of MPL reform legislation in past Congresses, and Congressman Lamar Smith (R-TX), the Chairman of the House Judiciary Committee, engaged in high-level discussions with PIAA and several medical organizations to develop effective MPL reform legislation. Those talks resulted in the January 24th introduction of a strong federal MPL reform bill which will serve as the foundation of MPL reform efforts this year.

The new MPL bill

The vehicle for reform will be the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2011. If you recognize the title, that is because it is the same as that of previous MPL reform bills passed many times by the U.S. House of Representatives over the last ten years. The bill will also have the same number as the one it had before.

As the new Congress begins, there is substantially more reason for optimism than we have had for several years.

Continued on page 18
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Continued from page 16
2007—H.R. 5. Also, just like its predecessors, the new HEALTH Act will contain the key elements of reform that the PIAA has long advocated:

■ $250,000 cap on non-economic damages
■ Scaled contingency fee arrangement for plaintiffs
■ Collateral source rule reform (evidentiary) with a ban on subrogation
■ Periodic payment of future damages
■ 3/1 statute of limitations.

Like earlier versions, this bill will also include additional reforms, such as limitations on punitive damages and abolition of joint and several liability in favor of a “fair share” rule. The bill will also (as it always has) show deference to state laws, allowing states to adjust the cap as they see fit (the “flexi-cap option”) and ensuring that states that have enacted reforms that are stronger than those in the HEALTH Act are allowed to keep them.

The PIAA is pleased that the HEALTH Act is again on the Congressional agenda, and will continue its longstanding support for this legislation. One thing that will change, though, is the approach we use in advocating for it. When the HEALTH Act was first introduced in 2002, the focus was on escalating premiums, a dwindling market, and the long-term solvency of the MPL insurance industry. Now, with frequency seemingly down, premiums holding steady, and dividends rising (even if only for the time being), we will have to emphasize that reform is still urgently needed, to improve accessibility to care and decrease the prevalence of defensive medicine. At a time when so much attention is focused on the federal budget deficit, it is perhaps most important to stress the budgetary savings that MPL reform can provide.

Fortunately, the Congressional Budget Office acknowledges the significant savings available if Congress were to enact effective federal MPL reforms. In an October 2009 letter to Senator Orrin Hatch (R-UT) on the potential impact of federal adoption of MICRA-based reforms, the CBO noted likely savings of $13.5 billion in the first five years after enactment, and $54 billion over a ten-year time period. While these savings are obviously not going to resolve the budget deficit problem, they are significant and we will be reminding Congress that they should not be ignored.

The House Judiciary Committee held a hearing on MPL reform on January 20, and the House Energy & Commerce Committee will likely also hold a hearing on the issue.

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on this issue in the coming months, leading to a vote on H.R. 5 sometime this spring. As Congress moves forward on the HEALTH Act, we will continue to keep PIAA members informed about what is happening and what can be done to help the bill’s progress toward passage in the House of Representatives.

Clarification for the PPACA: no new standards of care
While clearly our top priority, the HEALTH Act is not the PIAA’s sole focus of action in the 112th Congress. We will also press for legislation to make it clear that the new healthcare reform law (Patient Protection and Affordable Care Act) does not create new standards of care that could be used in MPL lawsuits. We have strong commitments from a bipartisan group of Representatives on this issue, although many details have not yet been resolved.

Identifying your priorities
In early January, we sent out a survey to all of the PIAA CEOs, to assess the legislative priorities of our members. At this time, the survey is still outstanding, but the issues listed in the survey include liability protections for volunteers, certificate of merit requirements, and expert witness standards. This survey will help guide our government relations focus throughout the next two years.

HCLA progress
Finally, it would be remiss not to mention the resurgence of the Health Coalition on Liability and Access (HCLA). Led by the PIAA, the HCLA is increasing its membership with new PIAA member companies and healthcare provider organizations, and taking significant action to promote MPL reforms. The HCLA Annual Meeting was held on Capitol Hill in late January, and featured several Members of Congress sharing their views on MPL reform. The meeting also gave participants the latest lobbying materials to share with their colleagues, so our community would present a united front on this issue. The HCLA also continues to expand “Protect Patients Now,” our online grassroots program whose intent is to ensure that Congress hears from its constituents about the urgent need for MPL reform.

The months ahead look promising for MPL reform advocates. Stay tuned for additional updates from the PIAA to make sure you know about everything that happens as the 112th Congress proceeds.
Zurich Study
New Details on Hospital Liability Claims
The frequency of hospital medical professional liability (MPL) claims is declining slightly, and severity is leveling off, according to a report released by Zurich. Each year, Zurich analyzes data comprised of its own claims information and claims self-reported to Zurich by hospitals seeking quotes for MPL insurance. The data, which contains 240,000 non-zero claims and $34 billion in undeveloped losses from approximately 1,600 hospitals, is used to identify trends for selected claims indices, including frequency and severity of claims and loss costs per occupied bed equivalent (OBE).

The size of the database allows Zurich to provide a snapshot of MPL claims frequency and severity for the hospital industry. The database does not include claims against individual physicians, nor is Zurich able to determine whether there was a physician component to the claim. However, the report does provide an overview of MPL trends in the hospital industry.

Frequency declined slightly
According to Zurich’s reports, claims frequency, calculated as the number of claims per 100 OBEs, declined slightly, compared with 2006, and is now at 1.96 claims per 100 OBEs (Figure 1). This is consistent with the gradual decline in frequency seen over the past several years. Although it is not possible to determine with certainty why frequency is decreasing, Zurich believes there are some factors that may be contributing to the decline. One such factor is the impact of the tort reform that has been enacted in many states. Plaintiffs’ attorneys are becoming more selective in

Susan Salpeter is a Healthcare Risk Management Specialist, Zurich Services Corporation, Chicago.
taking on new cases. They may be reluctant to take on “small” MPL cases in states where non-economic damages are capped. Texas, which enacted strict tort reforms in 2003, has seen much lower frequency since that time.

Another contributing factor in the decline in frequency may be the impact of risk management and patient safety initiatives. The Centers for Medicare & Medicaid Services, The Joint Commission, and other regulatory and advisory bodies have required, or strongly encouraged, hospitals to implement patient safety strategies and to follow certain clinical protocols. Zurich has seen a steady improvement in hospitals’ risk management and patient safety programs since 2004.

A 2009 Zurich internal analysis reviewed hospitals’ risk management scores over the past several years. Each hospital submission is reviewed and rated by a risk management consultant as part of the underwriting process. The review includes an evaluation of the hospital’s risk management/patient safety activities, claims management strategies, physician involvement in risk management activities, the strength of the nursing department, and investment in technologies such as computerized physician order entry. The analysis of risk management scores showed that hospitals have implemented many new risk management program activities. At the time of a review of risk scores in 2004, the following risk management strategies were determined to be part of a “better than expected” risk management program:

- Risk manager with more than 10 years’ experience in the field
- Patient safety rounds
- Participation in the Institute for Healthcare Improvement’s 100,000 Lives program
- Online incident reporting system
- Designated patient safety officer
- More than two patient safety initiatives per year.

Since 2004, these strategies have become common, and have led to a 10% increase in the risk-management ratings. The results may indicate a correlation between strong risk management and patient safety initiatives and a decrease in claims frequency.

**Claim severity—growing more slowly**

This year we found that overall claims severity, defined as the average amount per claim (not adjusted for inflation, for the purposes of this study), has stabilized over the past several years (Figure 2). The average annual increase over the past 11 years is 4% lower than last year’s finding, 6%.

It is important to note that the largest claims are not necessarily getting larger. Rather, it is the severity of the medium, or “typical” claim that is growing. This year, we see that Illinois, New York, and Pennsylvania continue to have the highest severity. Although the trend lines are similar, it can be seen how much these states have contributed to overall severity. Figure 2 also demonstrates the impact of tort reform on severity. Texas, once a state with higher than average severity, has had lower than average severity since 2003, when its tort reform became effective.

Although the frequency of large claims continues to rise, it is doing so...
more slowly than in previous studies (Figure 3). It is also noteworthy that the number of very large claims, those of more than $5 million, accounts for only 0.3% of all ultimate non-zero claims. Eight hundred out of 240,000 claims over the past 11 years have been greater than $5 million.

Indemnity vs. defense costs
Aggregate indemnity and expense payment ratios provide hospitals with a basis for determining how much expense costs contribute to overall costs. Expense costs are those that are allocated to the handling of the associated claim. As can be seen in Figure 4, both expense and indemnity payments have remained fairly flat. This year, the Zurich analysis shows a slight decrease in the percentage of total claim costs attributable to expenses, from 15.9% in 2006 to 14.8% in 2007.

Many healthcare organizations now encourage providers to disclose unanticipated outcomes, and in some cases, to apologize to patients and their families for medical errors. Others have instituted early-offer programs, in which settlement offers are made soon after the adverse event. Proponents of these programs believe they will lead to lower expense costs. We believe that these programs may be contributing to the slight decrease in expense costs, but there is not yet enough experience with them to determine their impact. In future studies, we will continue to monitor this issue.

Details on severity
The study also evaluated severity by type of organization structure, community description, and facility type. Our findings include:
- Nonprofit hospitals continue to have the lowest claim severity. Within the nonprofit segment, severity is significantly lower in church-based facilities than other organizational structures—by an average of 30%, over the course of this study.
- Urban hospitals consistently show the highest claim severity.
- Children’s hospitals continue to have the highest severity over time, while teaching hospitals, defined as those hospitals that are part of academic institutions or sponsor resident education programs, contribute significantly to overall severity.

Although the database is large, the results of the study have an inherent uncertainty, because certain assumptions had to be made with respect to loss development and trends. Estimates of future costs are limited by the ability to predict the course of future events, such as jury decisions, court interpretations, legislative changes, public attitudes, and social and economic conditions that may impact losses. To minimize much of the subjective component of claims evaluations, and to provide a basis for comparisons and trend evaluations, we used the years 1997–2007 for the study.

A full copy of the report is available online at www.zurichna.com.
On June 10, 2010, the Department of Health and Human Services’ Agency for Healthcare Research and Quality (AHRQ) announced grants to support efforts by states and health systems to implement and evaluate patient safety approaches and medical professional liability reforms. The demonstration and planning grants are part of the patient safety and medical liability initiative that President Obama announced to a joint session of Congress on September 9, 2009.

The President directed the Secretary of HHS to help States and healthcare systems test models that: (1) put patient safety first and work to reduce preventable injuries; (2) foster better communication between doctors and their patients; (3) ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits; and (4) reduce medical professional liability (MPL) premiums.

One grant recipient, Karen B. Domino, MD, MPH, Professor of Anesthesiology at University of Washington School of Medicine, Seattle, and a speaker at PIAA meetings and workshops, describes rationale and visions of her project to implement shared decision-making tools in surgical procedures in an effort to reduce medical liability.

Poor communication between physicians or other healthcare providers and patients is a risk to patient safety. When an adverse outcome occurs, the quality of physician-patient communication can contribute to whether a medical liability claim is filed and determine the outcome of that claim. Poor communication can also lead to patient dissatisfaction and complaints, burdening healthcare costs for complaint resolution.

Our project focuses on an important area of physician-patient communication, the process of informed consent. The informed consent process is critical to effective communication between physicians and patients for surgical and other procedural specialties. Inadequate informed consent is often a root cause of patient dissatisfaction, complaints, and medical liability following procedures.

Shared decision-making aids formalize and improve the informed consent dialogue, resulting in improved patient understanding of procedures, risks, and alternatives. Not only will this study in the University of Washington Health Care System (UW Medicine) improve physician-patient communication and patient knowledge, it will also yield important information on
the effectiveness and cost of shared decision-making tools in reducing patient complaints, risk management transactions, and liability in surgical care.

**MPL and physician-patient communication**

Only a small proportion of negligent adverse events actually lead to MPL claims. A sample of New York hospital records from 1984 revealed that only one out of eight adverse events associated with substandard care resulted in an MPL claim.¹ Matching individual clinical records with claims data, less than 2% of adverse outcomes from negligence were followed by MPL claims.² The severity of patient disability, not the occurrence of an adverse event or a medical error, was predictive of payment to the plaintiff.³ The findings suggest the role of other factors than "standard of care" to medical liability.

Communication failure between physicians and patients is an important element associated with medical liability.⁴⁻⁷ Patients who sue are more likely to be unhappy with the interpersonal relationship with their physician than the outcome of their care.⁵ Because physician characteristics were less determinant of lawsuits against surgeons, the informed consent process or disclosure of potential risks and errors may be key to effective surgeon-patient communication.⁸⁻⁹ In fact, the perceived withholding of explanation or information is a common reason why patients file a lawsuit.⁴⁻⁶

Some physicians are sued more frequently than others. A high-risk group of 2% to 8% physicians in a variety of specialties, including anesthesiology and surgery, accounted for more than 50% of medical liability claims.¹⁰ High-risk physicians were found to have inadequate communication skills with patients and their families, especially when a complication occurred.¹¹ A greater share of patient complaints in hospital units was associated with communication issues and perceived lack of humanness of the unit staff.¹² In a review of closed MPL claims against general surgeons, we previously found that in two-thirds of the claims, better communication with the patient could have prevented the lawsuit.⁷⁻¹³ The failure to communicate appropriately was the most important single behavioral practice pattern violation, accounting for 22% of claims (Figure 1).⁷

These findings indicate that improved communication may reduce patient dissatisfaction, complaints over their care or outcomes, and litigation. Informed consent represents one of the most
important times for communication between anesthesiologists and surgeons with patients that sets expectations for outcomes.

**Informed consent**

Informed consent is an ethical obligation of the practice of medicine and a legal requirement per statute and case law in all 50 states. It requires a thoughtful dialogue between physician and patient, wherein sufficient information is conveyed so that the patient can make an educated decision about the medical course of action. Twenty-five states and the District of Columbia use the “reasonable person” standard ("what a reasonable patient would consider pertinent in making an informed decision"), 32 states use the “professional practice” (i.e., what another physician in the community would disclose under similar circumstances), and two states are less clear.14

The 1975 Washington State Statute (Chapter 41.05 RCW), still in effect, requires discussion in language that a competent patient or his/her representative can reasonably comprehend, including the nature and character of the proposed treatment, anticipated results, and explanation of available alternative therapies. Disclosure of material risks (i.e., those that a reasonable person would want to know before making treatment decisions) of the recommended and alternative treatments is required. Material risks include risks that occur frequently, but have little long-term consequence, as well as risks that are rare but may result in serious, long-term morbidity or mortality.

Unfortunately, physicians often do not share the information patients need to make an informed decision. A study found that only 9% of patient decisions of more than 1,057 recorded patient encounters encompassing 3,552 clinical decisions met criteria for informed decision-making15. Similarly, only 2% of end-of-life decisions met criteria for informed decision-making16. In many surgical cases, the extent of informed consent is even more limited, with mere signing of the informed consent document taking place in lieu of a full discussion. Only 26% of surgical consent forms in 157 hospitals addressed the four key elements of informed consent (benefits, risks, alternatives, and educational information).17 Furthermore, the content of current informed consent documents is not easily understood by patients and their families.18

Differences in expectations between physicians and patients regarding outcomes of healthcare procedures often result in litigation. Inadequate informed consent of benefits and risks of procedures is an important underlying factor in this and can lead to perceptions of medical malpractice.19 Although lack of informed consent is rarely the sole reason for a lawsuit, it becomes an issue when associated with an adverse outcome. Issues of consent may arise from inadequate disclosure of the benefits and risks of the procedure, failure to obtain consent for a procedure, and failure to document refusal of care when a patient refuses medical advice, among others.

We previously analyzed closed claims from anesthesiologists and general surgeons to examine the role of informed consent in MPL. Informed consent was an issue in 10% of claims against anesthesiologists and 19% of claims against general surgeons. Despite these seemingly low proportions, up to two-thirds of anesthesia claims in which informed consent was an issue were of low severity. With a high cost of defense and indemnity associated with low-severity claims, these findings demonstrate a substantial opportunity to reduce claims for low-severity injury by improving the consent process.

**Shared decision-making**

Shared decision-making represents an empowering approach to actively engage patients in the treatment decision process.20 Characteristics of the shared decision-making process are shown in Figure 2.20 In 2007, the State of Washington added the option of shared decision-making to the statute dealing with informed consent.21,22 The legislation provides that if a competent patient or representative signs an acknowledgement of shared decision-making, this acknowledgement constitutes prima facie evidence of patient informed consent. Several other states are considering this form of legislation.

Shared decision-making tools have been shown to improve
patient knowledge of conditions and procedures as well as satisfaction with the decision process. A common educational tool known as a decision aid provides the information and considerations needed for patients to participate in shared decision-making. Figure 3 lists the 2007 Washington State Statute’s criteria of decision aids required for patient acknowledgement of shared decision-making.22

The Cochrane Collaboration conducted a meta-analysis of 55 randomized controlled trials of shared decision aids for people facing health treatment or screening decisions.23 Findings showed that the use of decision aids improved patient knowledge about their screening or treatment, satisfaction with reduced decisional conflict, and participation in the decision-making process. Aids also reduced the proportion of undecided patients and increased the proportion of patients who had accurate risk perceptions, compared to usual care. However, the significant effects of decision aids on health outcomes or other related outcomes such as resource use remain to be seen.

Shared decision-making has been advocated as a means to reduce unnecessary interventions for a particular medical condition, resulting in less geographic variation of procedures, improved quality of health, and reduced healthcare costs.21,24 Exposure to decision aids resulted in approximately 20% reduction in rates of elective surgery compared to usual care.23 Such benefit of patient decision aids could potentially improve health outcomes by reducing unnecessary procedures and healthcare costs.

However, research has yet to show if shared decision-making will reduce medical liability. In theory, a patient who is better informed, who is more satisfied with physician-patient communication, and who takes greater ownership of the decision process, would be less likely to file a lawsuit in the advent of a poor outcome. In Washington State, the shared decision-making legislation is also likely to reduce medical liability due to the quality of the burden of proof of informed consent. Documentation of shared decision-making serves as a robust layer of legal protection; the patient has the burden of rebutting the shared decision by clear and convincing evidence, a very high civil burden of proof that is difficult to overcome. Plaintiff attorneys may be less likely to pursue such claims, claims may be more easily defended, and litigation transactional costs reduced.

As part of the 2007 Washington State statute, a demonstration project was set up by the Washington State Health Care Authority at primary care sites to implement shared decision-making and decision aids in day-to-day clinical practice.25 This primary care project assesses patient understanding of treatment options for preference-sensitive health conditions, alignment between patient values and the care they receive, and implementation costs of shared decision-making in clinical practice for conditions such as breast cancer, coronary artery disease, prostate specific antigen testing for prostate cancer, and back pain.

Our project is distinguished by testing the integration of shared decision-making into a specialty care system directed at surgical and anesthetic care. We focus on prevention of liability with an assessment of patient complaints and risk management transactions after surgical procedures. We will also evaluate the effectiveness of education by healthcare practitioners.

**Informed consent communication and patient safety**

Informed consent with patient “teach-back” of key information about the proposed treatments or procedures is integral to the 2009 National Quality Forum’s (NQF) Safe Practices for Better Healthcare.26 The Consensus Panel was concerned about the frequency with which patients are not given adequate informed consent. As provider-patient communication failures are at the root of harm-inducing systems failures and human errors, the NQF Consensus Panel agreed that communication is key to preventing patient harm related to lack of informed consent.27

Preoperative education has been shown to improve patient outcome in the immediate postoperative period by reducing stress and pain and improving psychological well-being and satis-

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**Table**

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<tr>
<th>Criteria for Decision Aids Based on 2007 Washington State Statute</th>
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<tr>
<td>1. Provide high quality, balanced, up-to-date information, including:</td>
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<td>• Evidence-based risks and benefits of treatment and alternatives</td>
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<tr>
<td>• Limits of scientific knowledge about outcomes, if appropriate</td>
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<td>2. Clarify and sort patient values and preferences</td>
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<tr>
<td>3. Include guidance or coaching deliberation to improve patient participation in the decision process</td>
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Despite variation in the quality of studies involved, several meta-analyses showed a small-to-medium beneficial effect of preoperative psycho-educational interventions about recovery, pain, and psychological distress. However, the subjective perception of pain is dramatically influenced by anxiety and psychological factors, which may be amenable to preoperative education involving shared decision-making tools.

A systematic review of 11 studies in orthopedic patients found that preoperative education improved patient knowledge and decreased anxiety. A similar preoperative education study involving patients undergoing total hip or knee arthroplasty found improvements in anxiety, mental status, pain medication use, and length of stay. Compared to patients who lacked information, patients who had received preoperative education needed lower amounts of parenteral pain medications, were mobilized earlier, and reduced length of stay by two days. Because patients with a higher level of anxiety required more information, they may greatly benefit from educational interventions, including decision aids.

The benefits of patient education may also extend beyond the perioperative period. Preoperative patient education decreased the risk of hip dislocation in the first six months after total hip replacement. Patient education was effective at preventing recurrence of ulnar neuropathy at the elbow, particularly in patients with mild disease. On the other hand, patient education is likely to have little impact on many adverse conditions and may lead to less desirable outcomes, such as the over-diagnosis of postoperative wound infection by more informed patients.

The specialty ranked fifth in the total number of claims filed and fifth in the cumulative amount of payments to plaintiffs. The 8% MPL rate for an orthopedic surgeon is just behind the rates of general surgery and obstetrics/gynecology (12% each). Minor permanent injuries represented more than a quarter of total indemnity paid for orthopedic claims.

A large number of claims in orthopedic surgery are related to the informed consent process. Consent issues were involved in a large number of claims in orthopedic surgery, directly accounting for 17% of more than 9,000 MPL claims. Lawsuits for inadequate informed consent in the orthopedic area involved elective, not emergent, surgical procedures. Obtaining informed consent in the physician’s office (rather than in operative settings) and documenting consent in the surgeon’s notes that informed consent took place was shown to effectively reduce liability and payments.

Orthopedic surgeons are leaders among surgeons to endorse patient-centered care initiatives that enhance patient education and decision-making. The American Association of Orthopedic Surgery (AAOS) recently launched a patient-centered care initiative to improve patient education, physician-patient communication, safety, and quality of care. This initiative emphasizes that the patient, not the physician, should decide what’s best for him/herself, and that ensuring patient understanding of outcomes can reduce the risk of lawsuits and improve treatment compliance. Shared decision-making, which has been advocated as a means to reduce liability in orthopedic surgery, will contribute to achieving these goals.

Medical liability in orthopedic surgery
Orthopedic surgery is a high liability area that holds promise for participatory decision-making process. The 8% MPL rate for an orthopedic surgeon is just behind the rates of general surgery and obstetrics/gynecology (12% each). Minor permanent injuries represented more than a quarter of total indemnity paid for orthopedic claims.

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Study goals
This planning grant will implement shared decision-making for orthopedic surgery procedures in the University of Washington Healthcare System (UW Medicine). Shared decision-making tools for elective orthopedic procedures (e.g., total joint replacements and spine procedures) will be developed and implemented. Physicians will undergo training program for shared decision-making. We will evaluate costs; effectiveness of the informed consent process; patient understanding of risks, benefits, and alternatives of their procedure; patient satisfaction; and patient complaint and risk management transactions before and after implementation. This grant will generate pilot data to support a demonstration project of the influence of shared decision-making in the informed consent discussion and its influence on medical liability. In the future, we hope to partner with other institutions and medical liability insurance organizations both within and outside of the state of Washington.

For a complete list of the references cited in this text, go to www.piaa.us and click on Physician Insurer magazine.
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Patient Safety and Medical Professional Liability Claims—

The Missing Link
There have been so many patient safety organizations and initiatives in the past decade that they don’t all fit on the same scorecard. They have had mixed results and mixed reviews. Some improvement measures pass into standard practice; some are modified or discarded. Most initiatives and programs are a work in progress. Some observers say that patient safety is a movement that is just now gaining traction.

What role does medical professional liability (MPL) and risk management play in improving patient safety? In the Risk Management Department at LAMMICO, as in many PIAA member companies, we think we are the experts in reducing MPL risk. We believe that reducing risk and improving patient care are tied so closely together that you can’t do one without the other.

As CME providers, we tell our accrediting body, the Accreditation Council for Continuing Medical Education (ACCME), that reducing MPL risk by definition improves patient outcomes. It is apparent, every day, in our claims analysis and claims data—but can it be proven?

**The RAND study**

The RAND Corporation has published a report on a study that tested this very hypothesis: “Is Better Patient Safety Associated with Less Malpractice Activity? Evidence from California.” It is the first of a series of studies planned on this topic.

In this five-year study—2001 through 2005—the researchers admittedly and deliberately set out to compare apples and oranges. In one dataset, there are 365,000 “adverse events,” defined as harm to a patient from medical treatment. They are the patient safety indicators of in-hospital events captured by ICD-9 codes, including birth and obstetric traumas, accidental punctures and lacerations, postoperative pulmonary embolisms (PEs) and deep vein thromboses (DVTs), decubitus ulcers not present on admission, and hospital-acquired infections.

In the other dataset, there are 27,744 open and closed MPL claims against California physicians, 2001 through 2005. The claims are not limited to the hospital setting. These comprise all the claims from four major MPL carriers in California, covering the majority of the non-self-insured physicians.

Is there a relationship between the physician MPL claims and adverse hospital events?

The answer is a resounding yes! The study finds that claims track closely with adverse events over time, across counties, and across specialties, at a ratio of 3.7 claims to 10 adverse events. Specifically, if claims rise by 3.7 in a given year, adverse events rise by 10. If adverse events decrease by 10, then 3.7

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claims go away. The general surgery claims tracked adverse events most closely of all the specialties, and Ob/Gyn, the least. But even the Ob/Gyn claims tracked with a high degree of statistical significance.

This study is especially interesting because it does not attempt to analyze the causes of individual claims, as previous claims studies have done. The earlier claims studies have generally shown that the formula for an individual MPL claim is an undesired or adverse outcome, combined with a failure of physician behavior or communication. Many of these studies are quite labor-intensive, involving a detailed study of the claim files, medical records, and plaintiff depositions. In contrast, the RAND study makes an aggregate comparison of all claims against physicians compared with the aggregate of all in-hospital identified adverse events.

Physician claims include many in which the physician is not at fault. For example, they include claims that are attorney-related, claims for known complications, claims that are systems-related, and claims for which no damages are paid to the plaintiff.

Likewise, the in-hospital adverse events include many in which optimum care may have been rendered (PE/DVT after surgery), many where the physician was not at fault (birth injuries), and many that are not a common cause of claims (hospital-acquired infections, blood transfusion reactions). And yet the link remains.

The conclusions from the cause-of-claims studies and the RAND study are complementary, not contradictory. The cause-of-claims studies indicate that bad outcomes in combination with failures in physicians’ behavior or communication are strongly linked to claims. They also demonstrate that the communication/behavior failure has far more predictive value than the adverse event. Claims are the tip of the iceberg.

The RAND study shows that physician MPL claims are correlated strongly with in-hospital adverse events. Both support the idea that adverse events are a precursor to claiming, and that only a minority of adverse events will result in a claim. The new finding from the RAND study is this: it suggests strongly that reducing adverse events will reduce claims, and, for the first time, does so in a specified ratio.

There is another conclusion that both cause-of-claims studies and the RAND study support: blaming physicians is not the road to improvement. The RAND writers propose:

...that many preventable injuries result from complex systems failures; that most medical providers genuinely want to keep their patients safe; and that the combination of quality-improvement activities and root-cause analysis can be an effective tool for reducing the occurrence of injuries. By extension, improving safety performance also offers the potential for positive impact on the medical liability climate, and on the volume of malpractice litigation, across the United States.

The RAND study is rigorous, highly pertinent, and serendipitous to the goals of MPL risk management. It substantiates and complements our cause-of-claims studies. It lends weight to the claim that we are a great resource and potential ally, for other stakeholders, in improving patient safety.

Our trade association, the PIAA, has the largest independent claims database in the world. The PIAA produces important studies of MPL claims focused on identifying the causes of claims and making practical risk management recommendations that flow from the data.

To name just a few, PIAA claims studies have included the diagnoses of myocardial infarction, colorectal cancer, breast cancer, and most recently Aortic Disease. These PIAA claims studies are highly complementary to the recent body of medical literature on diagnostic error (see the article and reference list in “Diagnostic Error: What Claims Data Can Bring to the Table,” Physician Insurer, Third Quarter 2010).

The RAND study; the PIAA studies, and the peer-reviewed studies on claims and diagnostic error are gifts to MPL risk management. LAMMICO makes use of these studies, along with professional guidelines from medical specialty organizations, to create continuing medical education (CME) courses, offering premium-discount credit for completion. Taken together, these new studies are a rich resource for meeting the purpose of CME in identifying and closing physician practice gaps, while reducing our physicians’ MPL risk.

References
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The mission of the Safe Use Initiative, implemented November 2009, is for the Food and Drug Administration (FDA) to collaborate with public and private healthcare stakeholders to reduce preventable harm from FDA-regulated medications. On November 16 and 17, the FDA held a workshop to communicate the status of ongoing activities and the future vision for Safe Use Initiative projects. Physician Insurer spoke with Karen Weiss, MD, MPH, Program Director for the Safe Use Initiative, about the novel structure of the program and some potential plans for its future.

Q: How did you come to know about the PIAA?

A: We’ve already had contact with the PIAA over the last year. We have been doing a fair bit of outreach, to find out where various organizations are seeing harm, and what we might all do together to stop it. We contacted PIAA and a representative came to one of the Listening Sessions we held at the campus where we talked about the initiative and asked attendees for their thoughts about how to reduce preventable harm.

The Safe Use Initiative was implemented just a year ago. The whole idea behind it is that although the FDA, as a regulatory agency already has various programs to promote safe drug use as part of our regulatory mission, we believe we can do more. We can do that by stepping outside of that particular role, and working in a collaborative way with other groups working on healthcare—not just those that we regulate, which is primarily the pharmaceutical industry.

We are looking more toward a full collaboration with other segments of the healthcare industry, particularly because they are the ones that have a greater ability to influence behaviors and practices that will lead to safer use of medications than does the FDA.

Q: You’ve been inviting other organizations to suggest topics for discussion?

A: Absolutely. We want other groups to tell us where they see preventable harm from the medications that FDA regulates, and how we can form voluntary partnerships among stakeholders.

We see potential. But we are not there, at the front lines, like the providers who are managing the patient or working in the insurance industry and covering the cost of medication. They can help us see the problems, and identify solutions to them, within their particular healthcare setting or professional practice. We want to find what will be workable for them.

As part of the initiative we will collaborate not only with other government entities, such as CMS, CDC, AHRQ, and HRSA, but also health insurers, pharmacy benefits managers, medical societies, nursing organizations, and patient safety organizations.

Q: What is the plan for compiling and organizing the information?

A: We have launched a safe-use website at the FDA, for one thing, where we talk about what we have been working on, and provide updates on new potential opportunities for collaboration. We have an open docket, where we are soliciting input directly from the public.

We have also convened stakeholders who have knowledge about a specific topic for one-day meetings, to find out where we should best focus our energies to address a particular safety issue.

For example, we held a meeting recently on a fairly esoteric topic, but one that is very important because it is entirely preventable: fires in the surgical suite. Each year, there are from 100 to 600 surgical fires. Some are very minor—say, the drapes catch fire, and it is easily put out with water. But others are quite serious, and sometimes patients are seriously disfigured and may even die.

The meeting brought us together with our colleagues in medical device regulation. They regulate tools like the electrocautery units that create the spark, while FDA regulates the alcohol-based agents used to prep the skin, which add fuel to the fire, and the oxygen that contributes as well.

We think there are ways to develop interventions to work with the stakeholders—the professional organizations such as anesthesiologists, surgeons, and...
operating room nurses, the Joint Commission, CMS, and various fire-protection groups. We would like to learn what is already being done to prevent fires, and then identify what more can be done, again in a non-regulatory capacity. We want to identify the best interventions that will really solve this problem.

This is where we really need to be working, where we can provide assistance outside of our regulatory role.

Q: And you don’t have a menu of items as this time—because you’re waiting for suggestions from the outside?

A: Absolutely. Most people are used to the FDA coming down from the mountains, on high, in a sense, saying, “This is what thou shalt do, or we’ll be taking some enforcement action against you.” This new approach for safe use, voluntary, involving and working with stakeholders, is hard for some people to understand. They are so used to being in this sort of mode: “Just tell us what to do, FDA, and we’ll do it.” And we say, “No, not for this initiative. We want to hear from you. We want to work with you.”

We are working now on some medication safety issues that we are aware of, and that are reasonable for FDA to work on, like the operating room fires. But we really want to get broader input from the public, as to what would be appropriate areas for focusing our resources and our activities.

In the listening sessions that we have already done, many of the topics that we hear about pertain to very broad topics, one example being health information technology. We all agree that there are very serious problems in healthcare today, and we would certainly support measures to develop better health IT tools that will improve medication safety, and so on. But there is not much that we can really do in that arena, at least right now.

But it’s a bit hard, even under the Safe Use Initiative, to know how we can work to advance health information technology—where we would fit in. So we will more likely be tackling problems that are related to drugs, or drug-class specific. The broader a given problem is, yes, the greater an impact you can have, for public health, but the harder it is to figure out where you should intervene and how you are going to do that. If you start with something more specific, in a localized geographic area, you can develop something workable, implement something, and measure its impact and evaluate it. Then, you can decide whether to expand on it.

Q: Will the information you compile be disseminated—in scientific publications?

A: Yes. But we are most interested in learning what drives behaviors. How do you change them to make medications safer? That’s what we really want to accomplish. Even something like misuse of antibiotics, which is a terrible problem in medicine—many groups are working on that, but it’s still an issue.

If we can collaborate with parts of healthcare, on a particular medication safety area, and we can show—in a scientific and rigorous way, possibly through randomized studies—that implementing a particular intervention has an impact, that would be appropriate for a scientific publication.

Q: Where should people go to find the latest news on your program?


Q: Would you welcome information from our readers, on trends they see in their claims data?

A: Yes, absolutely. And in fact, we are already working with CMS on their claims data. But we would love to hear from the readers of Physician Insurer.
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BY MARK DUMOFF AND KEVIN BINGHAM

Engaging Patients, Empowering Doctors: Reducing the risk of MPL claims

A n article in the fourth quarter 2007 issue of Physician Insurer, “Avoiding the Next Medical Malpractice Crisis—Can We Shape Our Destiny?” noted that, according to research from the Healthcare Litigation Group of Stevens & Lee, lapses in communication and service are the main drivers of claim frequency and severity, not malpractice.

In today’s challenging social, political, and economic times, the role that the healthcare system plays in our daily lives has taken center stage all across America. Regardless of your political point of view, there is one thing we can agree on: meaningful change in our healthcare system is essential to reduce costs and improve quality and access to care for every American. Because tort reform is unlikely to be a component of this needed change, true collaboration between a patient and his physician, and the patient’s evaluation of the experience of care—as it happens, in real time—must become integral to every aspect of healthcare to mitigate risk.

Even the most compassionate, caring, and competent providers may find it difficult to singlehandedly improve a patient’s health. A truly effective doctor-patient relationship requires a collaborative effort among the entire care team of providers, clinicians, caregivers, patients, family members, and health plans. As IBM’s Global Director of Healthcare Transformation and President of the Patient-Centered Primary Care Collaborative Paul Grundy, MD, MPH, points out, IBM employees who are engaged in a happy, healthy, like-minded doctor-patient relationship frequently have a much better patient experience.

A positive patient experience translates to better patient compliance and healthier outcomes, making a clear pathway to a significant reduction in overall healthcare costs. For medical professional liability (MPL) insurers, a happy and well-informed patient population provides a welcome foundation for a claims-free environment.

The current environment

The healthcare system in the United States is fragmented, and, in any event, wasn’t set up to be patient-centered. Quality-of-care measurements done at the point of care and during the course of care have not kept pace with healthcare policy changes that make patients largely responsible for managing costs and improving quality. Therefore, quality measures that focus on patient experience in combination with educating and engaging patients and their families in their care, such as access to care, communication, self-management, and patient satisfaction, are sorely needed to improve outcomes throughout the healthcare delivery system.

Healthcare consumers face a wide range of challenges and changes, from higher costs and lower reimbursements to having to understand the fine details of their plans and the healthcare benefits provided in them. Patients may feel caught in the middle of numerous new missions and mandates. Research supports the notion that patients are experiencing greater dissatisfaction with their practitioners. Patients struggle with issues such as long wait times, limited interaction with their doctors, communication issues (e.g., respectful listening, clear communication, and patient follow-up, etc.), and difficulty in understanding the patient care plan (if they were even fortunate enough to receive one in writing).

Correspondingly, physicians and their clinical staff are constrained by lower reimbursements, challenging practice economics, and new, unfunded mandates. They rely on physician extenders (e.g., physician assistants, certified registered nurse practitioners, and certified registered nurse anesthetists) to increase capacity in an effort to improve the economics of their practice. Many physicians feel stressed and on guard, reacting to regulatory, quality compliance, and insurer administrative requirements; HIPAA procedures; MPL risk and premiums; the pressure to adopt electronic medical records (EMR); as well

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as balancing the business of health with the art of practicing medicine. The impact of these forces is serious and can pose serious threats to both healthcare providers and patients, not to mention suppressing clinician/patient communication contrary to established standards of care.

The doctor-patient relationship
There is a close relationship between patients’ degree of satisfaction with their physician and quality-of-care process measures. Physician concerns about MPL can affect the doctor-patient relationship, especially among high-risk specialties. Physicians and support staff who are engaged in their profession connect more effectively with their patients. Research shows that better communication leads to improved adherence and better health outcomes. These doctors know how to practice patient-centered care and have happier, healthier patients. Conversely, doctors and support staff, from clinical extenders to front desk clerks, who are dissatisfied represent a greater risk of errors in communication, writing prescriptions, and other elements of patient safety. Their patients, who are less likely to form a compatible and meaningful relationship with their doctors, may be more likely to consult a plaintiff’s attorney, instead of the doctor, when searching for answers on what they think went wrong in the delivery of their care.

Leveraging emerging technology
Fortunately, innovations in health information technology are now available to measure both patient and provider satisfaction within the context of the practice and the doctor-patient relationship. Research shows that if patients have positive feelings about their physicians, they are less likely to sue their doctors for malpractice. Utilizing real-time scientific patient experience survey tools and analysis provides clear metrics for assessing each patient’s attitude toward physicians and hospitals.

For MPL insurance companies, the advantages of leveraging patient and provider satisfaction data for underwriting, risk management, and loss prevention is clear. Since patient experience and quality measurement reporting is a key element in Centers for Medicare & Medicaid Services (CMS) requirements for physicians and hospitals, the value of types of survey tools is becoming increasingly recognized. MPL insurers are in a unique position to help their hospital and physician insureds begin tracking, understanding, and benchmarking their results.

More importantly, those insurers leading the charge in implementing these types of tools will have a “first movers” competitive advantage. For underwriting, the insurer would have immediate online access to the survey results for each physician and hospital. The underwriter could benchmark a physician’s satisfaction ratings against the other doctors in her practice, in her territory, or in her specialty. To the extent that a physician falls short in certain survey categories, the insurer would be in a strong position to recommend appropriate risk management and loss prevention actions (e.g., communication boot camp, online training). Physicians returning superior results can be rewarded with additional discounts and further incentivized to keep them. For insurers using advanced analytics, one can only imagine the additional “lift” the insurer could achieve by leveraging patient satisfaction ratings in their underwriting models by using simple, graphic dashboards.

Benefits of measuring patient experience
The benefits of applying metrics to the patient experience begin with the premise that a positive...
doctor-patient relationship leads to better communication and, from there, to better outcomes. Providing a constructive patient experience can lead to better adherence to treatment plans and self-care, increased patient loyalty, and more word-of-mouth referrals to the practice. Improving patient satisfaction can also lead to increased staff and physician satisfaction, a lower risk of being sued, and, ultimately, lower MPL premiums.

The possible benefits are itemized below:

**Insurer/Health Plans Impact**
- Risk mitigation: reduce frequency/severity of loss
- Reduce benefit (medical care) cost ratio
- Reduce SG&A expense ratio
- Increase retention rate
- Improve acquisition rate (Net Promoter Score)
- Compliance with anticipated government mandate

**Hospital Impact**
- Proactively manage risk
- Enhance quality of care while prospectively reducing patient length of stay
- Reduce medical expenses

**Employer Impact**
- Improve branding and public image
- Increase admissions/decrease re-admissions

**Better healthcare decisions**
- Healthier outcomes
- Fewer visits
- Less out-of-pocket.

**Conclusion**

The last decade has seen substantial investments in design, development, and testing of healthcare quality measures. While there has been progress in improving clinical outcomes, we are just beginning to scratch the surface in measuring the “softer side” of medicine: patient reported outcomes and comparable effectiveness. The Institute of Medicine’s report *Crossing the Quality Chasm* underscored the barriers to reaching a highly effective and efficient healthcare delivery system. The report stressed the critical role of the patient-centered model of care.

An effective doctor-patient relationship requires collecting and analyzing quality measures that focus on patient experience and adherence such as access to care, communication, self-management, and patient satisfaction. Only by gathering and reporting real-time insights about each patient’s experience will we enable physicians to fine-tune the quality of their services and enhance the mutual satisfaction of the doctor-patient relationships.

**Better communication leads to improved adherence and better health outcomes.**

In the end, we recognize the importance of collecting and analyzing feedback on performance. MPL insurers are in a unique position to help their hospital and physician insureds track, benchmark, understand, and address development areas through risk management and loss prevention actions. To the extent patient satisfaction increases, we believe the MPL industry will benefit, in lower frequency and severity of losses.
Medical professional liability (MPL) litigation has had a profound effect, not only on the cost of healthcare, but on the practice of medicine as well—to the point where doctors are now reluctant to treat certain diseases. Such is the case with retinopathy of prematurity (ROP). ROP is a progressive eye disease of the retinal blood vessels. The major physiological risk factors for ROP are low birth weight and early gestational age. ROP can result in severely impaired vision or full blindness.

Since it was first described in the medical literature 70 years ago, ROP has increasingly been a source of MPL litigation against hospitals and pediatric specialists, especially neonatologists and ophthalmologists. In the United States, the number of premature births since 1981 has risen significantly, and the incidence of this disease has increased, along with neonatal survivability.1

ROP MPL claims fall into the low-frequency/high-severity category. Many verdicts and settlements are greater than $1 million, and some occasionally much higher, including one of $15 million in 2001, one of $20 million in 2006 (that sent shock waves nationwide through pediatric hospitals and other hospitals with Level III Neonatal Intensive Care Units, where infants susceptible to ROP are treated), and one of $38 million in 2008, again involving twins. Like other cases involving children, ROP cases are difficult to defend because of the strong emotions and sympathies they evoke. These cases have a high profile in the legal and medical communities and in the media. Plaintiffs’ lawyers seek them out through the Internet.2 Many ophthalmologists avoid treating these patients due to fear of becoming a defendant in MPL litigation.3

This article will review:

- The physiological risk factors for ROP clinical presentation, and current treatment
- Significant barriers to diligent and timely diagnosis
- Recent developments in ROP litigation, including primary risk factors and the impact of large verdicts on the healthcare delivery system and on attending pediatric specialists and hospitals with Level III nurseries
- Risk management and patient strategies to prevent the communication errors and systemic problems that often result in litigation.

Risk factors for ROP
ROP occurs when premature birth disrupts the normal development of the blood vessels in the retina. The most significant risk factors for ROP are prematurity and low birth weight. The disease does not occur absent these factors.4

The risk of ROP is greatest for premature newborns with a birth weight of less than 1,251 grams and gestational age of less than 31 weeks.5 In fact, 80% of premature infants weighing less than 1,000 grams...
pounds) develop the disease, usually in both eyes. The number of premature infants at risk for ROP due to significantly low birth weight has risen since the 1980s, as advances in neonatal care have improved infant survival rates. Multiple births due to fertility treatments account for part of the 30% increase in premature births over the last two decades. But not all premature babies are at risk for ROP, and of those that do develop the disease, about 90% present with a mild case that resolves without therapy.

Of the approximate 4 million infants born in the United States every year, about 28,000 weigh 2¾ pounds or less. About 14,000 to 16,000 of those infants have some degree of ROP. Of those infants whose ROP progresses beyond the mild type, 85% respond to surgical treatment. An average of two out of every 100 ROP patients will experience permanent vision loss. Poor outcomes can occur, even with the very best of care.

The disease process
The vasculature of the retina begins to develop three months post-conception, and is complete by the end of a normal gestation period. In normal development, these blood vessels form at the optic nerve in the posterior of the eye, and then grow gradually to the edges of the developing retina where they will deliver nutrients and oxygen. In the last 12 weeks of gestation, the eyes develop rapidly.

When infants are born extremely premature, normal eye development can be disrupted. The blood vessels supplying the retina may cease growing, or they grow abnormally from the retina into the usually clear gel that fills the posterior portion of the eye. The retinal periphery then signals a need for nourishment, resulting in the development of abnormal blood vessels, which are fragile and can develop leaks, bleeding into the eye. Scar tissue may form and pull the retina loose from the eye’s inner surface. This retinal detachment is the primary cause of visual impairment and blindness for infants with ROP.

There still are significant gaps in modern medicine’s understanding of the development of ROP. Current knowledge of causative factors includes, beyond prematurity, low birth weight and supplemental oxygen administration; and more recent studies show a possible link to a genetic component.

Diagnosis and treatment
Until the 1980s, there was no treatment for ROP. Then came cryotherapy, an ophthalmologic surgical procedure. Surgical intervention will often stop the abnormal growth of blood vessels and significantly reduce the progression of ROP.

Treatment is dependent on timely diagnosis, based on retinal examination using binocular indirect ophthalmoscopy.
The window in which treatment of ROP will work can be narrow—a matter of weeks.

The eye examination is performed by a pediatric ophthalmologist in a Level III neonatal intensive care unit (NICU). The preferred method of treatment has shifted from cryotherapy to laser therapy, but both types of surgery destroy the periphery of the retina through ablation, which retards or reverses the abnormal growth of the vasculature that, untreated, can cause severe or total loss of vision. Unfortunately, the procedures permanently reduce peripheral vision—and they are not always successful. Even with flawless care, some patients lose their vision.

In 2010, ROP screening guidelines were based on those published in the journal *Pediatrics* in 2006 and promulgated jointly as a policy statement by the Section on Ophthalmology of the American Academy of Pediatrics, the American Academy of Ophthalmology, and the American Association for Pediatric Ophthalmology and Strabismus. These guidelines recommend screening eye examinations for:

- Infants with a birth weight less than 1,500 grams or gestational age of 30 weeks or less (as defined by the attending neonatologist) and selected infants with a birth weight between 1,500–2,000 grams or gestational age of more than 30 weeks with an unstable clinical course, including those requiring cardiorespiratory support and who are believed by their attending pediatrician or neonatologist to be at high risk should have retinal screening examinations using binocular indirect ophthalmoscopy to detect ROP.

Clinicians use other criteria as well in evaluating infants at risk. These include the location of ROP within the retina, the stage of the disease, and the observed presence of vascular tortuosity (called Plus disease).

Dr. James D. Reynolds, Children’s Hospital Buffalo, a leading ROP expert, says, “Plus disease is probably the single most important retinal finding in the prognosis of this disease and is now the essential finding influencing treatment decisions. Hence the single most critical determining factor in ROP is an examiner judgment call, with all the inherent problems associated with that.”

Dr. Reynolds correctly points out that these statements are guidelines and, as such, do not necessarily constitute a deviation from the standard of care, as long as what was done at the time was medically reasonable in the circumstances.

Telematic imaging holds promise for improved care and...
treatment of ROP, but continues to be studied for efficacy. At present, indirect ophthalmoscopy performed at the patient’s NICU bedside is the preferred approach to diagnosis. Thus, treatment of ROP involves careful monitoring of oxygen saturation levels, peripheral retinal ablation by either cryosurgery or laser surgery, and surgery for the repair of retinal detachment, although outcomes for retinal surgery of retinal detachment, although

Thus, treatment of ROP involves careful monitoring of oxygen saturation levels, peripheral retinal ablation by either cryosurgery or laser surgery, and surgery for the repair of retinal detachment, although outcomes for retinal surgery for detachment are poor. Research is still under way to optimize therapy for ROP, as current treatments have limitations and patients are invariably left with long-term effects, ranging from damaged peripheral vision to blindness.

ROP clinical management: challenges

The paramount issue for clinically managing ROP is timely identification of the disease and early treatment. Delays in either identification or treatment can be devastating and give rise to litigation. The number of infants requiring screening examinations has increased significantly, with more premature births and an expansion of the gestational-age criteria in the 2006 policy statement. The 2006 statement discusses the coordination and communication that must occur in each NICU between the neonatology and ophthalmologic services, and between the attending primary physicians, especially if the infant is transferred from a Level III NICU to a community hospital with either a Level I or II nursery. If the infant is discharged to the parents, the doctor (or others) must communicate the critical time window for follow-up eye examinations and potential for severe vision loss, including blindness, should those appointments not be kept. Timely ROP screening and follow-up care can be a challenge for many reasons:

- Patients are discharged prior to the initial examination.
- Patients are discharged prior to the follow-up date.
- Patients are too ill for the initial examination.
- Patients are transferred to another facility.
- Socioeconomic factors may inhibit and delay the caregivers in returning for follow-up visits.

ROP litigation

The history of ROP litigation tracks the evolution of the pediatric community’s understanding of the disease. The advent of the neonatal intensive care unit and administration of supplemental oxygen to premature infants treated in isolettes set the stage for the first wave of litigation. Until the 1980s, the major cause of ROP (then termed retrolental fibroplasia or RLF) was thought to be exposure of premature infants to high oxygen levels (hyperoxia). The chief allegation in these cases was negligent administration of appropriately high levels of supplemental oxygen for prolonged periods of time, or some variation thereof, such as failure to monitor oxygen levels by obtaining timely readings of blood gasses.

Then, in the 1980s, new technology made it possible to monitor oxygen levels in the blood continuously, through the use of intravascular and transcutaneous electrodes. ROP was thought to be controllable, if not preventable. But the increased survivability of very-low-birth-weight infants, as a result of other clinically significant developments, put more infants at greater risk of developing ROP. While prolonged exposure to high levels of oxygen remains a risk factor, prematurity alone is a primary risk factor, particularly when measured by very low birth weight and gestational age at birth. In fact, the incidence of ROP in the United States is not decreasing. It is a worldwide problem occurring anywhere the healthcare delivery system allows sophisticated treatment of low birth-weight premature neonates.

With the increased ability to assess and treat the eyes of these infants, the focus of ROP litigation has changed since the 1980s. The chief risk-management issue now is making sure that patients do not fall through the cracks and fail to receive either a timely initial eye examination or appropriate follow-up, particularly after discharge from the NICU to the parents or to another facility. Improper administration of oxygen is no longer likely to be an allegation in litigation.

In 2007, Dr. Reynolds reviewed 13 closed MPL claims from 1999 to 2006 in a diverse geographic distribution—cases in which he functioned as a paid consultant or had found in the literature (Table 1).

Table 1 Summary of Medical Care Issues in ROP in 13 cases

<table>
<thead>
<tr>
<th>Issue</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to refer/missed window of opportunity—inpatient vs. outpatient (neonatologist/pediatrician)</td>
<td>8</td>
</tr>
<tr>
<td>Failure to educate parents (neonatologist/pediatrician)</td>
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</tr>
<tr>
<td>Failure to oversee (hospital)</td>
<td>7</td>
</tr>
<tr>
<td>Failure to follow up (ophthalmologist)</td>
<td>6</td>
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<td>Failure to supervise (ophthalmologist/resident ophthalmologist)</td>
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<tr>
<td>Negligent examination/diagnosis (ophthalmologist)</td>
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<td>Negligent treatment (ophthalmologist)</td>
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<td>Rare but expected occurrence (ophthalmologist)</td>
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<tr>
<td>Zone III (ophthalmologist)</td>
<td>4</td>
</tr>
<tr>
<td>Issue of harm (all)</td>
<td>3</td>
</tr>
</tbody>
</table>

Table, used with permission.
According to Dr. Reynolds, recent cases chiefly follow two recurring fact patterns:

- A failure on the part of the neonatologist(s) and team in the NICU to appropriately refer a patient for an ophthalmology consult and screening eye examination.
- A failure by the ophthalmologist to properly follow and diagnose the patient, often due to clerical and/or administrative functions or lack thereof.12

Reynolds also found that those 13 cases frequently involved other issues, such as failure to educate the parents on the necessity of return visits, failure to supervise residents involved in care, and consistency of documentation. Ten of the 13 cases reviewed were settled (Table 2). Two that went to verdict resulted in awards ($15 million in 2001 in Texas and $6 million in New Jersey in 2004).

A study by Shelly Day et al., published in June 2009, reviewed 12 closed ROP MPL claims filed from 1987 through 2003 involving ophthalmologists insured by Ophthalmic Mutual Insurance Company (OMIC). Nine of the 12 cases involved litigation. Eight involved the failure to appropriately transfer the patient’s care between the NICU and the subsequent treating ophthalmologist in an outpatient setting, also an issue in Reynolds’ case reviews. The authors correctly assert that this is a “…weakness in the chain of care of premature infants” due to the complex interaction required between the neonatologist, ophthalmologist, nursing and other hospital staff, pediatrician, and the patient’s family.17

Another common issue identified in the OMIC claims study was “an inappropriate length of time between follow-up examinations.” Responsibility for appropriately timed follow-up examinations and appointments falls upon the ophthalmologist.17

Two trial verdicts in the last three years have potentially ratcheted up the economic valuation of ROP cases and focused more attention on ROP risk than ever before. The first was the Lee case from suburban Philadelphia in November 2006. The chief allegation was a failure to advise the parents of the need for timely follow-up examinations, which resulted in the child’s complete blindness. The jury award was $20 million.

This case sent shock waves through the pediatric community, especially pediatric hospitals, hospitals with Level III NICUs, pediatric ophthalmologists, and retinal specialists.18

The second case involved twins in Ft. Myers, Florida, in April 2008. The chief allegation in this case was that the ophthalmologist had failed to appropriately screen and diagnose ROP.

The defense asserted comparative negligence on the part of the mother for failing to bring the twins for their appointments. The jury awarded $38 million.

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### Table 2 Baseline Characteristics of 13 ROP MPL Cases12

<table>
<thead>
<tr>
<th>Case</th>
<th>State</th>
<th>Disposition</th>
<th>Party</th>
<th>Award</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>BW 780 g GA 25 wk</td>
<td>Missouri</td>
<td>Dismissed</td>
<td>Obstetrician/neonatologist</td>
<td>None $15,000</td>
<td>2000</td>
</tr>
<tr>
<td>BW 553 g GA 25 wk</td>
<td>Missouri</td>
<td>Settlement</td>
<td>Ophthalmologist</td>
<td>Discounted $5,500</td>
<td>2000</td>
</tr>
<tr>
<td>BW 1170 &amp; 1406 g GA 25 wk</td>
<td>Virginia</td>
<td>Settlement after trial</td>
<td>Ophthalmologist/neonatologist</td>
<td>$1.1 million $2.4 million</td>
<td>2000</td>
</tr>
<tr>
<td>BW 950 g GA 27 wk</td>
<td>Illinois</td>
<td>Settlement</td>
<td>Neonatologist</td>
<td>Defendant favor</td>
<td>2001</td>
</tr>
<tr>
<td>BW 790 g GA 27 wk</td>
<td>Illinois</td>
<td>Settlement</td>
<td>Ophthalmologist</td>
<td>Defendant favor</td>
<td>2001</td>
</tr>
<tr>
<td>BW 950 g GA 27 wk</td>
<td>Illinois</td>
<td>Settlement</td>
<td>Ophthalmologist/neonatologist</td>
<td>Non-suited plaintiff favor</td>
<td>2002</td>
</tr>
<tr>
<td>BW 787 g GA 24 wk</td>
<td>New Jersey</td>
<td>Settlement</td>
<td>Ophthalmologist</td>
<td>Defendant favor</td>
<td>2002</td>
</tr>
<tr>
<td>BW 1530 g GA 26 wk</td>
<td>New Jersey</td>
<td>Settlement</td>
<td>Obstetrician/neonatologist</td>
<td>None $15,000</td>
<td>2000</td>
</tr>
<tr>
<td>BW 1530 g GA 27 wk</td>
<td>New Jersey</td>
<td>Settlement</td>
<td>Neonatologist</td>
<td>Defendant favor</td>
<td>2001</td>
</tr>
<tr>
<td>BW 321 g GA 26 wk</td>
<td>New Jersey</td>
<td>Dismissed</td>
<td>Obstetrician/neonatologist</td>
<td>None $15,000</td>
<td>2000</td>
</tr>
<tr>
<td>BW 553 g GA 25 wk</td>
<td>Missouri</td>
<td>Settlement</td>
<td>Obstetrician/neonatologist</td>
<td>Discounted $15,000</td>
<td>2000</td>
</tr>
</tbody>
</table>

BW, birth weight; GA, gestational age.

In this series, ten of 13 cases were settled. Of those, seven were settled prior to trial or verdict, and three were settled after the verdict was rendered, but before the award amount was determined. Ten of the 13 involved a settlement. One was dismissed. One went to verdict and a large court-determined plaintiff award was partially vacated on appeal by one defendant. One went to verdict and a large court-determined plaintiff award in that case is still subject to appeal.

Not every defendant was assigned equal responsibility. Even in cases that result in a large award, individual defendants may be found to have no, or very little, responsibility.

Each of the 13 cases involves a complex series of events, in medically complicated patients dealing with an extremely complex disease. However, the actual medical facts in the cases are relatively straightforward. The interpretation of those facts and the non-documented testamentary facts usually decide such MPL cases.
planned to cease ROP treatments because of concerns over MPL exposure and inadequate reimbursement.\textsuperscript{21} MPL was cited by 67\% of the ophthalmologists who had ceased managing ROP cases as the reason why they had left this practice.\textsuperscript{22}

**ROP: risk management**

Perhaps the best publication on risk management for ROP is *Retinopathy of Prematurity: Creating a Safety Net*, written by Anne Menke, RN, PhD, the risk manager for OMIC, and available on the OMIC website. This document provides protocols for promoting patient safety and risk management for ROP care in the hospital and for outpatient ROP care. The article reviews such important issues as timeliness of the initial eye exam, developing a hospital ROP tracking system, providing caregivers with education, and discharge/transfer planning.\textsuperscript{23} It also provides sample documents for informed consent and caregiver education. The article by Day, Menke, and Abbot\textsuperscript{17} also promotes patient safety, with seven brief recommendations for helping to ensure patients receive appropriate ROP screening and follow-up.

The development of a formalized tracking system with responsibilities assigned and agreed upon by the healthcare team is an important component of patient safety and risk management, as is documentation of discharge instructions and consent to treatment. Many hospitals have designated an ROP coordinator, often a nurse, to handle this documentation responsibility, although this is only one possible approach to addressing the risk that ROP
patients may fall through the cracks in the healthcare system.

Conclusion

Timely screening, diagnosis, and treatment of premature infants with ROP are critical factors in mitigating litigation involving ROP. Recent cases have raised the stakes for these cases, and heightened the importance of creating coordinated care plans that are understood by all staff who are treating patients with ROP. Fortunately, the medical community is developing a growing body of literature on ROP. MPL claim issues, ROP.

References

2. See for example www.friedindo-briskyrop.com
19. Florida Jury Verdict Reporter, JN & CG as parents and legal guardians of DN and DN vs. C.E. Cox, M.D. (consolidated case), Lee Cty FL, Docket No.03-1698 and 03-1699.

For related information, see www.willis.com.

California: Leading the Nation, Once Again

L akewood (California) Regional Medical Center is offering patients emergency room reservations. For $15, a patient can book an appointment online between 90 minutes and two hours ahead of time. It’s one way for patients to avoid long ER waiting room waits.

If patients who book a reservation are not seen by a healthcare professional at the Lakewood, Calif.-based Tenet hospital within 15 minutes of their scheduled appointment, their booking fee will be refunded. Lakewood is one of eight southern California hospitals, and one of 23 hospitals and urgent care centers in eight states, using an online appointment system for emergency care, the Los Angeles Times reports.

Hospitals pay about $3,000 a month for the service and recoup the money as the volume of appointments grows. Loma Linda University Medical Center charges $25 for appointments at its 54-bed ER. About 400 patients have made appointments so far.

Medical directors across the country have been calling Dr. Robert Steele, division chief for adult services in the hospital’s ER.

“I think this is one of those things that’s going to sweep the country,” he said. Opponents of the system say that allowing people to pay to snag appointments encourages them to use ERs, although they may not need immediate care.

Steele attempted to justify the ERs serving patients without life-threatening situations. “Just because somebody comes to the ER and it’s not a life-threatening situation doesn’t mean they don’t need emergency services,” Steele said. “Sometimes we’re the only place that is open.”

—Los Angeles Times, January 30, 2011
Even when done properly, CT brain perfusion scans deliver a large dose of radiation—the equivalent of about 200 X-rays of the skull. But there are no hard standards for how much radiation is too much. The overdoses highlight how little some in the medical profession understand about the operation of these scanning devices and the nature of radiation injuries, as well as the loose requirements for reporting accidents when they are detected.—New York Times, July 31, 2010

At the Annual Meeting of the American Association of Physicists in Medicine (AAPM), held July 18-22, in Philadelphia, the presentations included a special symposium, “Medical Radiation and Patient Safety.”

We spoke with one of the presenters at the symposium, William Hendee, PhD, professor at the Medical College of Wisconsin and editor of the journal Medical Physics, to find out more about what the AAPM has done to minimize radiation dosages.

Q: What was discussed at the AAPM meeting, in terms of specific guidelines on radiation therapy and radiation dosages?
A: The meeting focused on how to provide guidance to operators of CT units, so that they use the right protocol for the right patient at the right time—to give them guidance on how to select the correct protocol.

Q: Is the operation of CT units standardized?
A: There is very little standardization. Equipment vendors have provided some minimum guidance on selecting protocols for specific examinations. But there are problems. First, they don’t cover all the possibilities, and second, they need to be adjusted for patient size—especially pediatric patients, but adult patients as well—and they need to address the ongoing evolution of the applications of CT.

Most of the protocols available now came from the vendors, and they were drafted when the vendors were doing the beta site testing of their units, so they don’t include up-to-date information. And in most institutions, the protocols are institution-specific, which means that they are not developed from a national approach to normalization.

Q: Do these machines need to be recalibrated regularly?
A: Yes, they do. There is no reason to think that the machine is going to lose its ability to perform. But it does need to be recalibrated. Quality assurance measures do need to be run on it frequently. Some of these are run daily; others, weekly or monthly. That’s not the problem.

The problem is that operators really don’t have good guidance, for a particular patient, with a particular type and model of machine. They need to be able to know: what is the best protocol that I can use, to acquire the necessary information for a diagnosis, at the lowest radiation dose to the patient? That information is sorely lacking in the field, and that is what we need to obtain.

Q: What prompted this effort? Had there been some safety problems?
A: If you look at the amount of radiation the average person received just 25 years ago, most of it came from background radiation. However, recent reports from the National Council on Radiation Protection Measurement and the International Commission on Radiation Protection have shown that in the United States, especially, the amount of radiation attributable to medical procedures has increased dramatically. Now, medical procedures account for about as much radiation exposure to the average individual as the natural background radiation.
ral background radiation.

The main reason for the increase in radiation exposure is CT examinations: CT examinations and nuclear medicine examinations—but especially CTs.

**Q:** CTs are becoming the new x-rays, aren’t they?

**A:** Sure they are. For lots of good reasons. CT is a powerful, powerful tool, and the applications are very beneficial to patients. The problem is, you need to apply a substantially greater radiation dose to the patient than the standard radiographic exam. We need to be sure that we can select the optimal procedure, so we can minimize the radiation dose to the patients.

Last November, I convened a meeting of CT experts. I asked the question, “What do we need to do—what are the main issues that we need to address—and what should we do to address them?”

Immediately, what emerged was this: People don’t know what the optimal procedures are. And so we decided to bring together, in one place, as many experts, from radiology, medical physics, radiological technology, equipment manufacturers, regulators, etc., to talk about how we might optimize protocols. And it’s these protocols that have begun to appear on the AAPM website.

**Q:** What can MPL insurers do to educate their physician insureds about these guidelines?

**A:** Well, let them know that some guidelines are available now, although it will take us awhile to complete the work. We are starting with CT perfusion. Then we will move on to angiography, and then the next exam after that. And so on. It will take us some time to compile the data we need. It’s not going to be an overnight process.

But industry is committed to it. There are five major manufacturers of CT equipment marketed in the United States: GE, Philips, Siemens, Toshiba, and Hitachi. They all sent representatives to our meetings. They are committed to getting this done.

Ultimately—we can’t do this just yet because we don’t have the data—insurers could say, we will pay for imaging procedures, but only if the providers used the guidelines on the AAPM website. Some insurers already insist that facilities operating imaging equipment be accredited, for reimbursement.

**Q:** What can MPL insurers do to promote quality imaging?
A: One way to defend against MPL claims is to be sure that your practice is accredited—that it has met peer-reviewed standards.

Physicians should encourage facilities to become accredited, because that is a good reference point for them in their defense, if they get sued.

Q: Are you trying to disseminate the protocols to the widest possible audience?
A: No. We initially thought about putting the protocols on a public access website. But the problem with that is liability. And we are a small band of professionals, medical physicists, with about 6,000 members in AAPM.

To put data up on a public website—where anybody can access that data and use it without any controls—would really make us vulnerable. So we decided that we should keep the protocols confined to the medical physics community. That way, we know that the people who are accessing the data are physicists. They can be the responsible parties in their organizations for applying the data, working with the radiologists and technologists.

Q: Moving on to the other hot topic, how are you responding to problems with radiation therapy?
A: The article in the New York Times by Walt Bogdanich on radiation accidents brought the problem to light. We’ve all been aware that this was an emerging issue. After we’d read the Times articles, we realized that we’d have to deal with it quickly.

As a consequence, the AAPM convened a meeting in Miami, “Safety in Radiation Therapy: A Call to Action,” on June 24, 2010.

As the technology of radiation therapy becomes more complex, and increasingly computer-driven, the capacity to know what is going on, as the patient is being treated, has become less and less.

The therapist is working in an environment that requires tracking several different computer screens, and several keyboards, while she is administering the treatment. But she does not have, right at the tips of her fingers, control over what’s happening. She doesn’t really know what’s going on.

In addition, the treatments are still designed and delivered by humans, and humans make mistakes. But the newer systems have become less fault-tolerant. What’s needed is a system that is configured such that, if an operator makes a mistake, she can catch the mistake before the radiation enters a patient. With increasing dependence on computer-driven systems, the ability to catch a mistake has diminished.

In some cases, for example, at Downstate Medical Center in New York or St. Vincent’s Hospital in New York, patients were killed by radiation. But there are also some near misses that we know about—errors that were made were corrected subsequently. Many of the recommendations that the AAPM has come up with focus on how we can return control of treatment delivery to the point of care—to the operator.

Continued on page 50
Q: Why has control over treatment increasingly been done by the equipment’s computers?
A: Radiation therapy has become technically more sophisticated, with greater precision, in the last ten years, with several technologies now incorporated into it.

We have increasingly sophisticated linear accelerators that can do more things. There is a new “conformal” radiation therapy, for example, that lets us shape the beam to the configuration of the tumor, more precisely.

And we can modulate the intensity of the radiation beam, using new multi-lead collimators designed to change configuration as the beam goes from one angle to another, so that it encompasses only the tumor.

What happened at St. Vincent’s Hospital was that the collimator malfunctioned, so the beam was wide open at all of the different orientations. That’s an error that should have been caught by the physicists. But they didn’t catch it.

That’s why I say that systems have to be fault-tolerant. There should be backup safety features that indicate, something is wrong with the way this machine is operating, or something is wrong with this treatment plan. An early warning system should be built into these systems—into the machine itself. And the vendors have agreed to this.

You can make all the claims you want about improved education, improved training, and improved diligence. All of those are important. But the first line of defense is the equipment itself.

Continued from page 49

Objective: To determine what components of a checklist contribute to effective detection of medication errors at the bedside.

Design: High-fidelity simulation study of outpatient chemotherapy administration.

Participants: Nurses from an outpatient chemotherapy unit, who used two different checklists to identify four categories of medication administration errors.

Main outcome measures: Rates of specified types of errors related to medication administration.

Results: As few as 0% and as many as 90% of each type of error were detected. Error detection varied as a function of error type and checklist used. Specific step-by-step instructions were more effective than abstract general reminders in helping nurses to detect errors. Adding a specific instruction to check the patient’s identification improved error detection in this category by 65 percentage points. Matching the sequence of items on the checklist with nurses’ workflow had a positive impact on the ease of use and efficiency of the checklist.

Conclusions: Checklists designed with explicit step-by-step instructions are useful for detecting specific errors when a care provider is required to perform a long series of mechanistic tasks under a high cognitive load. Further research is needed to determine how best to assist clinicians in switching between mechanistic tasks and abstract clinical problem solving.

PIAA Data Sharing Project

For more than two-and-a-half decades, the PIAA has maintained the Data Sharing Project (DSP), which is now the world’s largest independent medical professional liability research database. Storing detailed data on more than 270,000 medical and dental claims and suits, the database provides a rich resource for the investigation of the underlying causes and issues pertaining to medical professional liability claims.

These charts represent cumulative data from the Data Sharing Project. All DSP reports can be purchased online at www.piaa.us.

**Average Allocated Loss Adjusted Expense Payment Values — 2009 Dollars**

**Average Indemnity by Severity of Injury — Paid Claims Closed in 2009**

**Strength in numbers.** Your participation in the Data Sharing Project permits greater statistical power—and better information for patient safety. To learn more about participating in the Data Sharing Project, please contact P. Divya Parikh, dparikh@piaa.us.
If your medical professional liability (MPL) insurance company is a traditional state-regulated entity, you may not know about risk retention groups (RRGs). Established RRGs often operate very much like traditional insurance companies, but there are significant differences in how they are regulated. In the wake of a federal government research report on the risk retention industry, corporate governance emerged as a hot button. While this article will review the resultant corporate governance standards proposed for RRGs, these best practices in corporate governance can be applied to all MPL insurance carriers.

Risk retention groups, such as PIAA members Ophthalmic Mutual Insurance Company (an RRG), MedAmerica Mutual Risk Retention Group, Inc., and MCIC Vermont, Inc. (an RRG), are liability insurance companies licensed in and regulated by one state, but permitted to operate in all other states. Congress passed the Liability Risk Retention Act in 1986 (LRRA) in response to the hard market of the mid-1980s, when doctors and other groups of professionals needing liability insurance were having a difficult time obtaining or affording coverage. The LRRA requires that the owners of the RRG also be insureds and that they be engaged in similar businesses or activities. The benefit of this structure, for these similarly situated members, is to control and sustain their own efficient and cost-effective insurance programs. In large part, this is accomplished by avoiding onerous multi-state regulation. The industry segment that has used the LRRA to its greatest advantage is healthcare. Healthcare (e.g., physician, hospital, and nursing home liability programs) ranks first in gross written premium for RRGs.

In the last decade, the alternative-risk industry has tried to expand the scope of the LRRA, to cover property in addition to liability insurance. The most recent attempt is the legislation currently before Congress, the Risk Retention Modernization Act (H.R. 4802). In response to efforts to expand the LRRA and the hard market of the early 2000s, Congress requested that the Government Accountability Office (GAO) assess how well RRGs have achieved the original goals of the LRRA.

In August 2005, the GAO released its report. While offering the positive conclusion that “RRGs have had a small but important effect in increasing the availability and affordability of commercial liability insurance for certain groups,” the GAO did question whether the LRRA provides sufficient protection to insureds relating to RRG ownership, control, and governance. The GAO found that the LRRA’s partial preemption of state insurance laws has resulted in widely varying state regulatory standards. The fear of some regulators, wrought by a handful of RRG failures, was that some RRGs were being created for purposes other than self-insurance, such as making profits for entrepreneurs who might form and finance an RRG at the expense of the insureds. Therefore, the GAO

Kimberly Wynkoop is Legal Counsel, Ophthalmic Mutual Insurance Company, San Francisco, and Chair of the National Risk Retention Association Board; kwynkoop@omic.org.
recommended establishing minimum governance standards that would establish the insureds’ authority over management.4

The National Association of Insurance Commissioners (NAIC) took up this charge, and, in 2007, promulgated its “Governance Standards for Risk Retention Groups” (“the Standards”),5 with input from domiciliary and non-domiciliary state regulators, as well as RRG industry representatives. According to Jeff Johnson, attorney with Primmer, Piper, Eggleston & Cramer in Vermont, the “Review of the ‘Compilation of Comments’ submitted during the drafting process … reveals a good faith effort on the part of regulators and RRG representatives to develop reasonable Standards.”6

Robert H. Myers, an attorney with the Washington, D.C., law firm of Morris, Manning, and Martin and General Counsel of the National Risk Retention Association, agreed: “The NAIC Risk Retention Group Working Group’s corporate governance standards evidence the hard work and common sense utilized in the drafting process. The result is workable standards that embody the principles of fiduciary responsibility and member/shareholder involvement and control.”7

While the Standards were developed to address the needs of RRGs, they are based on governance standards for public corporations, and the principles derive from state laws on a board of directors’ fiduciary responsibilities.7 Many RRGs already practice these Standards; they may just need to do a better job in documenting and reporting their compliance. Others will need to begin to develop and then implement these policies, procedures, and practices, realizing that it will likely increase the responsibilities of the board of directors, and may cause the RRG some additional costs. RRGs will have to determine whether their current board members have the desire and capabilities to carry out these new responsibilities.8 If not, a change in leadership may be required. However, with additional education and training (and, possibly, some compensation for the additional time commitment involved via stipend, board meeting fees, etc.), current leadership may be happy to take up this charge.

NAIC Governance Standards for RRGs
The Standards require that the boards of directors of RRGs have a majority of “independent directors.” But who is considered independent? The Standards define independence as having no “material relation-
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FIRST Q UARTER 2011

Insurance and willing to participate on their boards of directors. Member-insured board members are firstly doctors, but also truckers, short-rail operators, professionals without much, if any, previous liability insurance experience.

Directorships are often volunteer positions that demand considerable time in both learning and in actual governing and decision-making. To furnish the necessary expertise, service providers such as captive managers or legal counsel may be elected to serve on the board. Generally, this is not a problem, but if the manager or counsel provides a substantial amount of work to a low-revenue RRG, the fee threshold for a “material relationship” might be met. This is an intended consequence, of course, as the Standards were developed in part to avoid faulty judgments by directors unduly influenced by management or consultants, or a board made up of such.

The board’s determination regarding director independence must be disclosed to its domestic regulator annually.

The next section of the Standards also addresses service provider control issues. It requires that the term of any “material” service provider
Finding a competent auditor, familiar with RRG requirements and willing to work with smaller-budget clients, can be daunting.

A Board Member's Duties

- Know enough about the RRG's business to exercise independent judgment, make informed policy decisions, and monitor management's performance
- Understand insurance accounting, reserving, investment strategy, and premium calculation
- Educate new members, and retrain all current members, in all corporate governance policies: conflicts, confidentiality, duties, etc., and to follow these dictates:
  - Do not act for your own benefit
  - Do not act other than to advance the welfare of the corporation
  - Disclose conflicts of interest
  - Make business opportunities available to the corporation
  - Document disclosures and decisions
- Board Meetings
  - Ask management to provide materials for review in advance
  - Be educated and prepared for meetings
  - Allow ample time for thorough discussion
  - Encourage open dialogue and debate
- Participate actively in industry associations to learn from peers
- Seek independent advice regarding significant transactions and conflicts
- Make inquiry into potential problems, until satisfied that management has dealt with them appropriately.

contract shall not exceed five years, and that such contract's renewal requires the approval of the majority of the RRG's independent directors. Such contracts must be terminable at any time, with notice, for cause. A contract is deemed “material” if the amount to be paid under such contract is at least 5% of the RRG’s annual gross written premium or 2% of its surplus, whichever is greater. Service providers are defined as including captive managers, auditors, accountants, actuaries, investment advisors, lawyers (excluding defense counsel, unless their fees are "material"), managing general underwriters, or other parties responsible for underwriting, rating, claims adjusting, or the preparation of financial statements.

To enter into a contract with a service provider who meets the definition of "material relationship," above, the insurance commissioner must be notified and not disapprove. With smaller-revenue RRGs, or ones operating in a localized area such that they may use only one or a handful of firms, they may bump up against the fee threshold, requiring board approval in an area (the review and approval of contracts) previously left to internal management or the captive manager. Board members will need the expertise on company operations to understand the role of service providers and to evaluate their performance.8

The Standards require that an RRG have a written policy in its bylaws that meets various requirements for insured proof of ownership, setting of governance standards, evaluation of management, approval of service provider fees, and approval of the RRG’s goals regarding the compensation, performance, and continued engagement of officers and service providers. Although time and expense must be put in to rewrite the bylaws, this requirement only stipulates that the RRG document, and make public to its insureds and regulators, via its bylaws, the governance standards already required elsewhere in the document.

The audit committee: requirements

The Standards require that the RRG establish an audit committee, with a charter defining its purpose and responsibilities, another layer of oversight to guarantee the independence of the board. (The Standards do permit the domestic regulator to waive the audit committee requirement, if the RRG can demonstrate that is impracticable and that its board is able to accomplish the purposes of the audit committee.) The audit committee must be composed of at least three independent board members. Non-independent board members may participate in the committee’s activities, but cannot be members of the committee. In sum, the audit committee assists the board in its oversight of the integrity of financial statements, compliance with legal and regulatory requirements, and the qualifications, independence, and performance of service providers. The committee must meet with the independent auditor, with and without management, to review the RRG’s financial statements and supervise the annual audit, ultimately reporting its findings to the board. Its charge requires that committee members be well versed in insurance financial reporting and legal matters, as well as insurance underwriting and claims processing.8

This may require RRGs to appoint more outside directors with this sort of specialized knowledge or additional training for its current directors.

The charter also requires that the external auditor rotate the lead audit partner, as well as the reviewing audit partner, so that neither performs audit services for more than five consecutive years. Finding a competent auditor, familiar with...
RRG requirements and willing to work with smaller-budget clients, can be daunting. When an RRG finds an excellent firm, there may be only one lead partner and one reviewing partner that are qualified. While understanding the arguments for periodic rotation, RRGs may be loathe to begin the search anew for a comparable audit firm to replace its current firm.

Role of directors
The Standards require that the RRG adopt and disclose governance standards that explain director qualifications, elections, responsibilities, compensation, orientation, education, evaluation, and access to management and independent advisors, as well as the management succession plan. Likely, the bylaws of the RRG already contain much of this information on director election and responsibilities. However, the RRG may not have articulated their orientation, education, and evaluation processes. This requirement may motivate RRGs to improve their board educational programs and ensure follow-through. Likewise, management succession may be a to-do item that boards have left on the back burner. Because they are required to have a written standard for succession in place, boards will have to tackle this complex issue and emerge better prepared for unforeseen staffing issues or external disaster.

Even before embarking on any written governance standards, RRG directors, like all corporate directors, should be well aware of their duties. The fundamental duty of directors is to manage the corporate enterprise, also known as the duty to manage or duty of oversight. Broadly, this involves selecting competent senior management, establishing norms and procedures, formulating strategy, and carefully and continuously monitoring the performance of senior management and the enterprise itself. The other duties of directors dictate how they perform this fundamental function. These include the duty of loyalty and care, discharging their duties in good faith and in a manner the director reasonably believes to be in the best interests of the corporation. Directors also have an obligation to be candid—furnishing all of the relevant information for decision-making to those affected—and of confidentiality as well.

Directors should also exercise sound business judgment, i.e., act on an informed basis, in good faith, and in the honest belief that the action taken is in the best interest of the corporation. It is reasonable for board members to rely on management’s, outside professionals’ and auditors’ advice, provided that they have a reasonable basis for such reliance.

These duties must be further delineated in a Standards-required code of business conduct and ethics. The code applies to the officers and employees of the RRG as well as the directors. The code must address issues such as conflicts of interest, corporate opportunities, confidentiality, fair dealing, protection and proper use of assets, legal compliance, and reporting of illegal or unethical behavior. RRGs may already have such a code. If not, there are many examples of business codes online and more are available through industry groups.

With regard to the documentation requirements, you may find that you already have all of the components.

Accountable Care Organizations and MPL

For ACOs to be successful, Congress should provide safe harbors for adherence to evidence-based clinical practice guidelines and subsidized reinsurance that is made conditional upon meeting certain patient safety goals.

The goal of providing a safe harbor for ACOs that adhere to evidence-based guidelines is to strengthen the weight of clinical guidelines during litigation. It could help prevent or lead to the dismissal of claims that lack merit. It would also likely reduce defensive medicine because providers would have more confidence about the legal standard of care.

The idea of government-subsidized MPL reinsurance is that ACOs that meet certain conditions, such as improving patient safety, would receive subsidized reinsurance or stop-loss coverage on claims that exceed a certain threshold. This would offer an additional incentive to providers to improve quality and safety.

Fact sheet, from the Medical Group Management Association

Continued on page 58
Is there a better way to manage loss reserve volatility?

The essential measure of an insurance company’s solvency can be found in its loss reserves. Yet estimating these reserves involves a great deal of uncertainty, particularly for medical professional liability insurers. Milliman consultants can help. We bring an uncommon level of insight to the management of loss reserve volatility, employing the latest tools and drawing on 60 years of experience to extract more meaningful information from your reserve data.

For a unique perspective on this issue, read the article “Understanding, then managing, loss reserve volatility” on milliman.com. Type “reserve volatility” in the search box.

milliman.com
Continued from page 56

require that the captive manager of the RRG, or its CEO, promptly notify the domestic regulator if he or she becomes aware of any material noncompliance with any of the RRG’s governance standards. The domestic regulator may take appropriate regulatory action against any director or officer of the RRG, or its captive manager, pursuant to its laws and regulations, if the RRG or captive manager violates the governance standards. Captive managers in most domiciles already have a duty to report financial irregularities or hazards; the Standards just elaborate on this theme by requiring notice of noncompliance with the broader governance standards.

While the Standards may not be perfect, RRGs can benefit from the Standards’ requirement that they implement or document the current application of these stringent corporate governance guidelines. This, in turn, will increase the acceptance of RRGs by nondomiciliary states and provide a good educational opportunity for regulators of nondomiciliary states to learn more about the management of RRGs.7

Conclusion

As mentioned before, a new bill, H.R. 4802, the “Risk Retention Modernization Act,” was introduced in Congress March 10, 2010. The National Risk Retention Association and other industry groups combined to support this legislation, which would let RRGs write property coverage and would also facilitate dispute resolution among the states and RRGs, through the Treasury Department. An important component of this legislation is the inclusion of corporate governance standards, which closely mirror the NAIC Standards. In this way, the legislation would redress what, according to the GAO, the LRRA lacks: sufficient protection to insureds in regard to RRG ownership, control, and governance. These standards would be applicable to all RRGs under federal law, and would not require domiciliary state-by-state adoption, as happens with NAIC Standards. Some states may hold off in implementing the NAIC Standards while this legislation is pending. However, it is never too early to begin to implement and document the best practices outlined in the Standards.

For those who would like to learn more about the complex history of the NAIC’s role in the regulation of RRGs, there is a timeline tracing it all, at the PIAAs website (www.piaa.us) in the Physician Insurer magazine section.

References

1. 15 USCA 3901-3906.

Coming in the next issue of “Physician Insurer”—One hospital’s safety program

Overall, Henry Ford Health System has cut hospital-related infections by 22% since the beginning of its No Harm Campaign. During the past year, this decrease has been led by focusing on Clostridiun difficile bowel infections.

The marked improvements are the result of a stepped-up focus on all hygienic practices. These range from the most basic—hand washing—to better isolation of infectious patients, enhanced tracking of antibiotic use through specialized system-wide pharmacy software, and the use of a chemical “antibiotic lock” in catheters used to treat kidney dialysis patients.

This “lock” procedure alone has reduced dialysis-related bloodstream infections by two-thirds since the start of the No Harm Campaign, bringing Henry Ford into compliance with national benchmark standards.

Practices to reduce medication-related harm in Henry Ford hospitals have focused on those drugs posing the highest risk to patients—insulin to control blood sugar, narcotics for pain control, and blood thinners to prevent clots. This focus led to a new protocol for tight control of diabetic blood sugar. The new controls have cut incidents of hypoglycemia by 45% at Henry Ford Hospital alone.

Another pilot program, dealing with anti-clotting medications and their use, has slashed the risk of related patient hemorrhages by more than 80%, since it was launched by Henry Ford Hospital in 2008.
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- **State of the States**—Hear a discussion on current market conditions for MPL carriers. The panelists will address the challenges in the rapidly changing healthcare environment, and discuss strategies PIAA carriers can use for ongoing success.

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- **The Challenge of Emerging Risks and Defending Dentists**—In this session, a practicing attorney will provide insights into the challenges and experiences in defending dental clients who use original and/or unique treatment protocols.

- **How to Minimize the Risk of Using Social Media in the Dental Practice**—This session will tell dentists how to minimize the risk of adverse reviews on social media sites, and what they can do to counter any defamatory statements published there.

- **Avoiding Liability and Penalties Due to Changes in Law and Technology**—The session will offer strategies for avoiding penalties under new HIPAA/HITECH Act rules, risks from practicing in teaching and hospital settings, potential liability for “failure to consult,” and frequently litigated dental/medical issues.

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A New Low

By Eric R. Anderson

In case you haven’t heard, there is a new kind of investment making the rounds in the financial world. (And in these tough times, with money market funds begrudging less than 1%, who wouldn’t want a new and lucrative kind of investment?)

What is this new option, you ask? Well, large banks, hedge funds, and private investors are investing in other people’s lawsuits. Yes, that’s right. Every day, hundreds of millions of dollars are funneled into legal actions like medical professional liability (MPL) lawsuits—in the hope of sharing in the potential value of unresolved plaintiff and defendant, based on the potential award that would come with a plaintiff verdict.

Now, some people—me included—would take this as a sign of some sort of apocalypse. Think about it for a minute. We have devolved from a society where litigators chased down ambulances to try and secure a hefty payday (at least the attorney and his ancillaries with large sums of capital had to have some physical contact) to one where financial investors still like the upside of gambling on an MPL claim.

The reality is that firms like the entities that now invest in litigation can use savvy lawyers to assess how a professional liability claim might be favorably inclined toward the corporate defendant. So the potential of new funds, from investors, they would assert, just serves to level the playing field.

But we in the MPL world believe otherwise. Our industry has had a target on its back for years. We know that MPL claims are big business and that trial lawyers, regardless of the economic condition of their client, will in fact pursue some claims at almost any cost. Further, we know that MPL claims evoke sympathy, and that sympathy in turn evokes large payments. So even if the data shows that we win cases that go to trial about 70% of the time, the litigation investors still like the upside of gambling on an MPL claim.

Eric R. Anderson is Director of Public Relations and Marketing at the Physician Insurers Association of America; eanderson@piaa.us.
At BMS we’ve spent the last 25 years building a dedicated healthcare team which understands the needs of physician insurers. We ask the right questions, we act on the answers and we use our technical resources and market knowledge to find you the most appropriate, cost effective solution. In a world where very few risks are standard, our specialists will work with you to get the right result.

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