Claims by Specialty: a look at PIAA national closed claim data

by Laura Hale Brockway, ELS

The following is a compilation of medical malpractice claim data from 2003 to 2012, submitted by 24 member companies of the Physician Insurers Association of America (PIAA). The PIAA is a trade association of liability insurance companies that insure more than 60% of private practicing physicians.

TMLT submits claim data to the PIAA data study, but these data are reported in a codified manner. Names are not reported.

The PIAA database is the largest independent source of medical liability data in the world. Since 1985, 278,280 claims from 28 specialties have been reported to PIAA. For all claims, 29 percent (Continued on page 2)
were closed with indemnity payment, with an average indemnity payment of $325,914. The total indemnity paid out on behalf of all physicians in the database is $8.2 billion.¹

The following report highlights the three most prevalent medical misadventures per specialty along with the three most prevalent patient conditions associated with the misadventure. These conditions are those presented to the physician at the time of the alleged incident.

What follows is not meant to be an in-depth analysis, but a snapshot of claims by specialty. This information is designed for use as a risk management tool to inform physicians about the nationwide risk trends for their specialty.

**Anesthesiology**
Most prevalent medical misadventures and associated patient conditions:

1. No medical misadventure²
   - pregnancy
   - back disorders including lumbago and sciatica
   - brain damaged infant

2. Improper performance
   - back disorders including lumbago and sciatica
   - pregnancy
   - musculoskeletal disorders and symptoms affecting neck region

3. Problems with patient monitoring in surgery
   - displacement of intervertebral disc
   - coronary atherosclerosis
   - back disorders including lumbago and sciatica

**Cardiovascular and Thoracic Surgery**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - coronary atherosclerosis
   - chronic ischemic heart disease
   - aortic aneurysm

2. No medical misadventure²
   - coronary atherosclerosis
   - chronic ischemic heart disease
   - aortic aneurysm

3. Failure to recognize complication of treatment
   - coronary atherosclerosis
   - symptoms involving abdomen and pelvis
   - aortic aneurysm

**Cardiovascular Diseases (Nonsurgical)**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - coronary atherosclerosis
   - acute myocardial infarction
   - chest pain, not further defined

2. Errors in diagnosis
   - acute myocardial infarction
   - chest pain, not further defined
   - aortic aneurysm

3. No medical misadventure²
   - coronary atherosclerosis
   - acute myocardial infarction
   - heart disease, not further defined

**Dermatology**
Most prevalent medical misadventures and associated patient conditions:

1. No medical misadventure²
   - dyschromia
   - acne
   - malignant neoplasms of the skin

2. Improper performance
   - dyschromia
   - malignant neoplasms of the skin
   - acne

3. Errors in diagnosis
   - malignant melanoma
   - malignant neoplasms of the skin
   - disorder of skin and subcutaneous tissue

**Emergency Medicine**
Most prevalent medical misadventures and associated patient conditions:

1. Error in diagnosis
   - symptoms involving abdomen and pelvis
   - acute myocardial infarction
   - appendicitis

The PIAA database is the largest independent source of medical liability data in the world.
2. No medical misadventure
   - symptoms involving abdomen and pelvis
   - chest pain, not further defined
   - acute myocardial infarction

3. Improper performance
   - symptoms involving abdomen and pelvis
   - open wound of fingers
   - dyspnea and respiratory abnormalities

**Gastroenterology**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - benign neoplasms of the colon or large intestine
   - symptoms involving abdomen and pelvis
   - calculus of gallbladder or bile duct

2. Errors in diagnosis
   - malignant neoplasms of the colon and rectal region
   - regional enteritis, colitis
   - symptoms involving abdomen and pelvis

3. No medical misadventure
   - symptoms involving abdomen and pelvis
   - regional enteritis, colitis
   - hemorrhage of gastrointestinal tract

**General and Family Practice**
Most prevalent medical misadventures and associated patient conditions:

1. Error in diagnosis
   - acute myocardial infarction
   - malignant neoplasms of the female breast
   - appendicitis

2. No medical misadventure
   - alopecia
   - back disorders, including lumbago and sciatica
   - symptoms involving abdomen and pelvis

3. Improper performance
   - calculus of gallbladder or bile duct
   - admission or office treatment for sterilization
   - back disorders, including lumbago and sciatica

**General Surgery**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - calculus of gallbladder or bile duct
   - cholecystitis
   - inguinal hernia

2. No medical misadventure
   - symptoms involving abdomen and pelvis
   - calculus of gallbladder or bile duct
   - inguinal hernia

3. Errors in diagnosis
   - malignant neoplasms of the female breast
   - appendicitis
   - symptoms involving abdomen and pelvis

**Gynecology**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - endometriosis
   - genital prolapse
   - disorders of menstruation and other abnormal bleeding from the female genital tract

2. No medical misadventure
   - benign neoplasms of the uterus
   - pregnancy
   - female infertility

3. Errors in diagnosis
   - malignant neoplasms of the female breast
   - neoplasms of the female breast (unknown if malignant or benign)
   - symptoms involving abdomen and pelvis

**Internal Medicine**
Most prevalent medical misadventures and associated patient conditions:

1. Errors in diagnosis
   - malignant neoplasms of the bronchus and lungs
   - acute myocardial infarction
   - malignant neoplasms of colon and rectal region

2. No medical misadventure
   - acute myocardial infarction
   - chest pain, not further defined
   - symptoms involving abdomen and pelvis

Since 1985, 278,220 claims from 28 specialties have been reported to PIAA.
3. Failure to supervise or monitor case
   - diabetes
   - decubitus ulcer
   - obesity

**Neurology (Nonsurgical)**
Most prevalent medical misadventures and associated patient conditions:

1. Errors in diagnosis
   - headache
   - occlusion and stenosis of cerebral arteries
   - convulsions

2. No medical misadventure^2
   - back disorders including lumbago and sciatica
   - headache
cerebrovascular accident

3. Improper performance
   - back disorders including lumbago and sciatica
   - displacement of intervertebral disc
   - headache

**Neurosurgery**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - displacement of intervertebral disc
   - back disorders including lumbago and sciatica
   - disc disorder of unspecified region

2. No medical misadventure^2
   - displacement of intervertebral disc
   - back disorders including lumbago and sciatica
   - subarachnoid hemorrhage (not following injury)

3. Errors in diagnosis
   - back disorders including lumbago and sciatica
   - fracture of vertebral column
   - displacement of intervertebral disc

**Obstetric and Gynecologic Surgery**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - pregnancy
   - admission or office treatment for sterilization
   - brain damaged infant

2. No medical misadventure^2
   - pregnancy
   - brain damaged infant
   - delivery of normal, single gestation

3. Errors in diagnosis
   - malignant neoplasms of the female breast
   - ectopic pregnancy
   - pregnancy

**Ophthalmology**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - cataracts
   - myopia
   - retinal detachments and defects

2. No medical misadventure^2
   - cataracts
   - retinal detachments and defects
   - moderate to severe visual impairment

3. Errors in diagnosis
   - retinal detachments and defects
   - glaucoma
   - cataracts

**Orthopedic Surgery**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - generalized or localized osteoarthrosis
   - disorder of the joint, not including arthritis
   - fracture of the femur

2. No medical misadventure^2
   - spondylosis and inflammatory spondylopathy
   - generalized or localized osteoarthrosis
   - disorder of the joint, not including arthritis

3. Errors in diagnosis
   - disorder of the joint, not including arthritis
   - fracture of the foot
   - fracture of the tibia or fibula

---

For all claims, 29 percent were closed with indemnity payment, with an average indemnity payment of $325,914.
Other Nonsurgical Specialties
(Includes Podiatry, Physical and Rehabilitative Medicine, and Hospitalist)
Most prevalent medical misadventures and associated patient conditions:

1. Errors in diagnosis
   • displacement of intervertebral disc
   • fracture of vertebral column
   • malignant neoplasms of the bronchus and lung

2. No medical misadventure
   • back disorders including lumbago and sciatica
   • disorder of the joint, not including arthritis
   • no abnormal condition or treatment encounter

3. Improper performance
   • back disorders including lumbago and sciatica
   • bunion
   • disorder of the joint, not including arthritis

SPECIALTY GROUP STATISTICS
Cumulative Data from January 1, 2003 – December 31, 2012

<table>
<thead>
<tr>
<th>SPECIALTY GROUP</th>
<th>CLOSED CLAIMS</th>
<th>PAID CLAIMS</th>
<th>% PAID TO CLOSED</th>
<th>INDEMNITY PAID</th>
<th>AVERAGE INDEMNITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANESTHESIOLOGY</td>
<td>3,982</td>
<td>1,086</td>
<td>27.27</td>
<td>$397,959,070</td>
<td>$366,445</td>
</tr>
<tr>
<td>CARDIOVASCULAR &amp; THORACIC SURGERY</td>
<td>3,006</td>
<td>713</td>
<td>23.72</td>
<td>$229,932,059</td>
<td>$322,485</td>
</tr>
<tr>
<td>CARDIOVASCULAR DISEASES (NONSURGICAL)</td>
<td>2,529</td>
<td>502</td>
<td>19.85</td>
<td>$148,736,856</td>
<td>$296,289</td>
</tr>
<tr>
<td>DERMATOLOGY</td>
<td>1,098</td>
<td>278</td>
<td>25.32</td>
<td>$59,339,273</td>
<td>$213,451</td>
</tr>
<tr>
<td>EMERGENCY MEDICINE</td>
<td>3,687</td>
<td>887</td>
<td>24.06</td>
<td>$293,385,809</td>
<td>$330,762</td>
</tr>
<tr>
<td>GASTROENTEROLOGY</td>
<td>1,880</td>
<td>338</td>
<td>17.98</td>
<td>$112,886,665</td>
<td>$333,984</td>
</tr>
<tr>
<td>GENERAL &amp; FAMILY PRACTICE</td>
<td>9,425</td>
<td>2,321</td>
<td>24.63</td>
<td>$148,736,856</td>
<td>$287,844</td>
</tr>
<tr>
<td>GENERAL SURGERY</td>
<td>9,335</td>
<td>2,770</td>
<td>29.67</td>
<td>$863,406,329</td>
<td>$311,699</td>
</tr>
<tr>
<td>GYNECOLOGY</td>
<td>1,279</td>
<td>324</td>
<td>25.33</td>
<td>$91,296,288</td>
<td>$281,779</td>
</tr>
<tr>
<td>INTERNAL MEDICINE</td>
<td>13,785</td>
<td>2,984</td>
<td>21.65</td>
<td>$982,055,569</td>
<td>$329,107</td>
</tr>
<tr>
<td>NEUROLOGY (NONSURGICAL)</td>
<td>1,626</td>
<td>386</td>
<td>23.74</td>
<td>$160,898,197</td>
<td>$416,835</td>
</tr>
<tr>
<td>NEUROSURGERY</td>
<td>2,131</td>
<td>598</td>
<td>28.06</td>
<td>$262,609,105</td>
<td>$439,146</td>
</tr>
<tr>
<td>OBSTETRIC &amp; GYNECOLOGIC SURGERY</td>
<td>11,566</td>
<td>3,681</td>
<td>31.83</td>
<td>$1,530,697,387</td>
<td>$415,837</td>
</tr>
<tr>
<td>OPHTHALMOLOGY</td>
<td>2,476</td>
<td>632</td>
<td>25.53</td>
<td>$174,742,315</td>
<td>$276,491</td>
</tr>
<tr>
<td>ORTHOPEDIC SURGERY</td>
<td>7,791</td>
<td>2,078</td>
<td>26.67</td>
<td>$542,275,394</td>
<td>$260,960</td>
</tr>
<tr>
<td>OTHER NONSURGICAL SPECIALTIES</td>
<td>2,096</td>
<td>492</td>
<td>23.47</td>
<td>$152,470,484</td>
<td>$309,899</td>
</tr>
<tr>
<td>OTORHINOLARYNGOLOGY</td>
<td>1,710</td>
<td>580</td>
<td>33.92</td>
<td>$164,606,498</td>
<td>$283,804</td>
</tr>
<tr>
<td>PARAPROFESSIONAL</td>
<td>537</td>
<td>135</td>
<td>25.14</td>
<td>$35,903,388</td>
<td>$265,951</td>
</tr>
<tr>
<td>PATHOLOGY</td>
<td>726</td>
<td>229</td>
<td>31.54</td>
<td>$75,851,994</td>
<td>$331,231</td>
</tr>
<tr>
<td>PEDIATRICS</td>
<td>2,315</td>
<td>611</td>
<td>26.39</td>
<td>$241,179,137</td>
<td>$394,729</td>
</tr>
<tr>
<td>PLASTIC SURGERY</td>
<td>2,903</td>
<td>722</td>
<td>24.87</td>
<td>$133,490,813</td>
<td>$184,890</td>
</tr>
<tr>
<td>PSYCHIATRY</td>
<td>820</td>
<td>121</td>
<td>14.76</td>
<td>$23,590,222</td>
<td>$194,961</td>
</tr>
<tr>
<td>RADIATION THERAPY</td>
<td>362</td>
<td>102</td>
<td>28.18</td>
<td>$37,991,714</td>
<td>$372,468</td>
</tr>
<tr>
<td>RADIOLOGY</td>
<td>6,470</td>
<td>1,763</td>
<td>27.25</td>
<td>$614,468,369</td>
<td>$348,536</td>
</tr>
<tr>
<td>RESIDENT / INTERN</td>
<td>13</td>
<td>2</td>
<td>15.38</td>
<td>$175,000</td>
<td>$87,500</td>
</tr>
<tr>
<td>UROLOGIC SURGERY</td>
<td>2,434</td>
<td>647</td>
<td>26.58</td>
<td>$206,433,352</td>
<td>$319,062</td>
</tr>
<tr>
<td>TOTALS</td>
<td>96,454</td>
<td>25,223</td>
<td>26.15</td>
<td>$8,220,528,193</td>
<td>$325,914</td>
</tr>
</tbody>
</table>
Otorhinolaryngology
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - sinusitis
   - desire for plastic surgery
   - deviated nasal septum

2. No medical misadventure
   - sinusitis
   - deviated nasal septum
   - diseases of the upper respiratory tract (including pharynx, larynx, and vocal cords)

3. Errors in diagnosis
   - malignant neoplasms of the larynx
   - malignant neoplasms of the pharynx and pharyngeal region
   - sinusitis

Paraprofessional (Non-Physician Health Care Professionals)
Most prevalent medical misadventures and associated patient conditions:

1. Errors in diagnosis
   - appendicitis
   - malignant neoplasms of the bronchus and lung
   - asthma

2. Medication errors
   - asthma
   - allergic rhinitis
   - sinusitis

3. Improper performance
   - allergic rhinitis
   - open wound of knee, leg, or ankle
   - disorder of the external ear

Pathology
Most prevalent medical misadventures and associated patient conditions:

1. Errors in diagnosis
   - malignant neoplasms of the cervix
   - malignant neoplasms of the female breast
   - malignant melanoma

2. No medical misadventure
   - no abnormal condition or no treatment encounter
   - malignant neoplasms of the female breast

3. Improper performance
   - malignant neoplasms of the colon and rectal region

Paraprofessional (Non-Physician Health Care Professionals)
Most prevalent medical misadventures and associated patient conditions:

1. Errors in diagnosis
   - meningitis
   - appendicitis
   - specified nonteratogenic anomalies

2. No medical misadventure
   - brain damaged infant
   - routine infant or child health check
   - meningitis

3. Improper performance
   - circumcision
   - brain damaged infant
   - respiratory problems in newborn

Plastic Surgery
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   - desire for plastic surgery
   - hypertrophy of breast
   - hypertrophic and atrophic conditions of skin

2. No medical misadventure
   - desire for plastic surgery
   - dyschromia
   - congenital anomaly of the skin and integument

3. Failure to communicate/instruct patient
   - desire for plastic surgery
   - specified disorders of the breast
   - malignant neoplasms of the female breast

Psychiatry
Most prevalent medical misadventures and associated patient conditions:

1. No medical misadventure
   - depressive disorder, not further defined

“Medical misadventure occurs when there is no allegation of inappropriate medical conduct, but the claim has legal merit because of associated issues.”
• neurotic disorder, not further defined
• schizophrenia

2. Medication errors
• depressive disorder, not further defined
• schizophrenia
• bipolar affective disorder

3. Failure to supervise or monitor case
• depressive disorder, not further defined
• neurotic disorder, not further defined
• major depressive affective disorder

**Radiation Therapy**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   • malignant neoplasms of the female breast
   • malignant neoplasms of the prostate
   • malignant neoplasms of the back, flank, or trunk

2. Errors in diagnosis
   • malignant neoplasms of the bronchus and lungs
   • fracture of the vertebral column
   • malignant neoplasms of the female breast

3. No medical misadventure
   • malignant neoplasms of the female breast
   • malignant neoplasms of the bronchus and lungs
   • malignant neoplasms of the prostate

**Radiology**
Most prevalent medical misadventures and associated patient conditions:

1. Errors in diagnosis
   • malignant neoplasms of the female breast
   • malignant neoplasms of the bronchus and lungs
   • neoplasm of the breast, unknown if malignant or benign

2. No medical misadventure
   • malignant neoplasms of the female breast
   • neoplasm of the breast, unknown if malignant or benign
   • malignant neoplasms of the bronchus and lungs

3. Improper performance
   • malignant neoplasms of the female breast
   • back disorders including lumbago and sciatica
   • symptoms involving abdomen and pelvis

**Urologic Surgery**
Most prevalent medical misadventures and associated patient conditions:

1. Improper performance
   • calculus of kidney and ureter
   • disorder of penis
   • admission or office treatment for sterilization

2. No medical misadventure
   • calculus of kidney and ureter
   • malignant neoplasms of the prostate
   • disorder of penis

3. Errors in diagnosis
   • malignant neoplasms of the prostate
   • disorder of male genital organs
   • disorder of urethra and urinary tract

**Sources**

2. As defined by the PIAA, no medical misadventure occurs when there is no allegation of inappropriate medical conduct, but the claim has legal merit because of associated issues, such as problems with medical records, consent issues, communication between physicians, vicarious liability, product liability, etc.

**TMLT submits claim data, but these data are reported in a codified manner. Names are not reported.**
OBJECTIVES

At the conclusion of this educational activity, participants should be able to:

1. describe the new rules regarding delegation to midlevel professionals;
2. identify key differences between prescriptive authority agreements and standing delegation orders;
3. explain the new rules related to nonsurgical medical cosmetic procedures;
4. discuss rule changes related to copies of electronic medical records for patients; use of local and regional anesthetics in the office; and locum tenens leaving medical practices.

COURSE AUTHOR

Dan Ballard, JD is a partner with Ballard & Simmons, LLP. He received a Bachelor’s of Arts Degree with honors from the University of Texas and a Juris Doctorate with honors from the University of Texas School of Law. He was admitted to the State Bar of Texas in 1983. Mr. Ballard has spoken extensively on risk management and medical malpractice defense issues to physicians throughout the state.

DISCLOSURE

Dan Ballard has no commercial affiliations/interests to disclose related to this activity.

TARGET AUDIENCE

This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for medical liability.

CME CREDIT STATEMENT

Physicians are required to complete and pass a test in order to earn CME credit. A passing score of 70% or better earns the physician 1 CME credit.

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. TMLT designates this enduring material for a maximum of 1 AMA PRA Category 1 Credit™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

PRICING

The following fee will be charged when accessing this CME course online at www.tmlt.org/cme.

Policyholders: $10
Non-policyholders: $75

ETHICS STATEMENT

This course has been designated by TMLT for 1 credit in medical ethics and/or professional responsibility.

INSTRUCTIONS

The Reporter CME test and evaluation forms must now be completed online. After reading the article, go to www.tmlt.org/cme. Log on with your myTMLT user name and password to access the course. Follow the online instructions to complete the forms and download your certificate.

If you do not have a myTMLT account, please call customer service at 800-580-8658 ext. 5050.

Questions about the CME course? Please call 877-880-1335.

ESTIMATED TIME TO COMPLETE ACTIVITY

It should take approximately 1 hour to read this article and complete the questions.

RELEASE/REVIEW DATE

This activity is released on February 10, 2014 and will expire on February 10, 2017. Please note that this CME activity does not meet TMLT’s discount criteria. Physicians completing this CME activity will not receive a premium discount.
INTRODUCTION
In the summer of 2013, the Texas Legislature passed a significant package of legislation relating to the regulation of physician practices. The legislation became effective on November 1, 2013 and the Texas Medical Board (TMB) then adopted new rules relating to the legislation.

The most significant change imposed by the new rules involves the creation of the “prescriptive authority agreement” (PAA) as the tool now used to document the prescribing authority delegated to a specific midlevel professional.

The other major rule change relates to the details of hands-on physician interactions with patients undergoing minor cosmetic procedures, such as Botox injections. Other rule changes involve providing copies of electronic medical records to patients; use of substantial doses of local and regional anesthetics in the office; locum tenens leaving medical practices; and the operation of pain management clinics.

This article will help you understand how these rules apply to you, what the new rules mean, as well as helping you develop strategies for putting the new rules in place in your daily practice. By enhancing your knowledge of these rules, you can reduce your exposure to disciplinary actions by the TMB.


The rules can also be viewed at the TMB website, http://www.tmb.state.tx.us/rules/rules/bdrules.php

DELEGATION TO MIDLEVEL PROVIDERS
Eliminated requirements
Regarding delegation to mid-level professionals, several requirements from the old rules have been eliminated. These include:

1. 10 percent chart review at satellite clinics;
2. 10 percent on-site presence of physician at satellite clinics;
3. no Schedule II prescribing under any circumstances by midlevels;
4. 75-mile restriction on proximity of satellite clinics with midlevels; and
5. the limit of delegation to no more than four midlevels (or their full-time equivalents).

Understanding TMB Rule 193, the new midlevel delegation rule, begins with a clear appreciation that virtually all authority of a midlevel professional must be delegated in an individualized written document that defines the parameters of the midlevel professional’s authority to act. When any type of problem arises involving the care given by a midlevel professional, the TMB will request a copy of the written documentation that provides the delegation of authority to the midlevel professional to prescribe drugs and devices, as well as the additional documentation that provides authority to undertake other medical activities. Failure to have the appropriate delegation documentation will result in a sanction by the TMB.

The general intention of the new rules is to ensure that in most situations (except for some hospital-based practice situations), a formal PAA must be used to define the details of the delegation/supervision arrangement between the physician and the midlevel professional.
Interestingly, the new rules that describe the use of PAAs state that these agreements are to be used to delineate prescribing authority. The new rules are not clear about how other delegated authority must be delineated, such as for examinations, formulating working diagnoses, ordering tests, and making referrals to consultants. Presumably then, all of these other tasks need to be delegated through written protocols and standing delegation orders, which can either be separate documents or can be included in a PAA.²

Before discussing the details of what must be included in the new PAA, it is helpful to look at the larger framework into which these agreements fit. In the discussion below, you will note that the new designation for nurse practitioners is “advanced practice registered nurse” or “APRN” and this new designation will be used in this article.

**New limit of delegating to seven midlevel professionals**

The new rules allow for delegation of up to seven midlevel professionals.² If part-time midlevel professionals are being used, a physician may delegate to the “full-time equivalent” of seven midlevels. While new Rule 193 does not define “full-time equivalent,” the TMB would likely apply the definition provided in Rule 185.16, which is “no more than 50 hours per week.”³ The seven-midlevel limit does not apply to a practice serving a medically underserved population and does not apply in some hospital-based practice scenarios.⁴

**Hospital-based practitioners may qualify to delegate to more than seven midlevels and may not need PAAs**

The new rule provides for several categories of hospital-based physicians who qualify for an exemption to the new seven-midlevel limit. These physicians also qualify for an exemption from the requirement of having a PAA with each midlevel professional in this hospital-based setting.⁵

These exemptions will not extend to any midlevel professionals who are working in a freestanding clinic or practice of a hospital. Unfortunately, the new rules do not specify what is meant by the term “freestanding.” For the purposes of this rule, if in doubt, assume that a clinic or practice is freestanding from the hospital and that the freestanding clinic will have a limit of seven midlevels to whom you can delegate.⁶

Physicians who take advantage of this exemption from either the seven-midlevel limit or from the requirement of the use of PAAs may do so only in one hospital. At other hospitals, they will need to abide by the usual rules on delegation set out below.⁶

Note that an important advantage of falling under the hospital-based exemption is that the face-to-face meetings and/or remote electronic meetings that are required as part of the PAA quality assurance plan will not be required. However, it is still critically important that the delegating physician be able to demonstrate in a hospital-based practice that they are adequately supervising their midlevel professionals. The details of hospital-based supervision and quality assurance are not set out in the new rules.

The categories of hospital-based physicians who qualify for exemptions from the seven-midlevel limit and the PAA requirement are as follows:

1. the medical director or chief of medical staff of the hospital in which the midlevel practices;
2. the chair of the hospital’s credentialing committee;
3. a department chair in which the physician assistant or advanced practice registered nurse practices; or
4. a physician who consents to the request of the medical director or chief of medical staff to delegate prescribing.⁶

This categorization is a carry-over from the old rule. However, even for physicians who have been using the exemption under the old rule, it is important to understand that in order to practice under this exemption to the requirement for having a PAA, the hospital must instead have its own formalized, written policies in effect to govern the delegation of authority in this context (both for prescribing and for all other types of medical decision making). These formalized policies can be in the form of “a physician’s order, standing medical order, standing delegation order, or other order or protocol developed in accordance with policies approved by the facility’s medical staff or a committee thereof as provided in facility bylaws.”⁶

When developing these hospital-approved protocols or standing delegation orders, be sure to refer to the detailed definitional requirements in Rule 193.2(16) and (19).⁷ Each of the physicians for whom a midlevel professional will be seeing patients must have consented to the midlevel seeing their patients for them. In a call-coverage situation in which a first physician is on-call for a second physician, the second physician must have specifically given consent for his or her patients to be seen by the midlevel professional.⁷
**Delegation in long-term care facilities**

While delegation to midlevel professionals working in long-term care facilities appears to be given special status, once all of the exceptions are applied it becomes clear that delegation to midlevels in a long-term care facility has essentially all of the same requirements and restrictions as though the physician were delegating in an in-office setting.

The medical director of a long-term care facility is allowed to delegate to midlevel professionals by using “a physician’s order, standing medical order, standing delegation order, or other order or protocol developed in accordance with policies approved by the facility’s medical staff or a committee thereof as provided in facility bylaws.” However, other physicians practicing at a long-term care facility who are not the medical director must use the new PAA with each midlevel professional.²

If the medical director of a long-term care facility chooses to be exempt from the requirement of using PAAs, he or she will instead need to adopt protocols or standing delegation orders. The definitional requirements for such protocols or standing delegation orders are as extensive as the requirements for PAAs. (7) If the medical director chooses this exemption, the exemption will be allowed for only two long-term care facilities.³

All physicians practicing at a long-term care facility, including the medical director, are limited to delegating to a total of seven midlevel providers (and this total includes midlevels at any other facilities at which the delegating physician may also be practicing).

As was true in the context of hospital-based delegation, an advantage to the physician of coming under the long-term care facility exemption is that the quality assurance meetings that are required under a PAA are not specifically required if the exemption is used. Again, however, it is important that delegating physicians be able to demonstrate that they are adequately supervising their midlevel providers.

**Prescriptive Authority Agreements (PAAs)**

The new PAA — as outlined in the recently adopted rules — appears to be the Legislature’s and TMBs attempt to clarify the requirement of having a written document that clearly and concisely sets out the understanding between an individual physician and a specific midlevel professional in contract-like terms. Practically all of a midlevel professional’s authority must flow by delegation from a specific physician, and the general terms of that delegated authority must be stated in writing in a clearly identifiable document. In most circumstances, this document will be a PAA.

A physician and a midlevel professional must have a PAA in place for all circumstances of practice except for some hospital-based practices (and possibly some long-term care facilities, as described above).

**Practice tip:** Because the TMB adopted rules governing the new PAAs and in doing so has set forth the board’s expectations for the specific items that need to be covered in a PAA, the best practice for physicians in virtually all scenarios is to use PAAs for delegation of authority to midlevels rather than trying to claim an exemption and use “protocols” or “standing delegation orders.”

Additionally, in assessing whether your delegation documentation is adequate, you should examine a few hypothetical malpractice situations that could come up in your practice with your midlevel professional. You should then look at whether your delegation documentation provides at least general guidance to the midlevel about how that general type of medical situation should be handled.

The new rules are very specific about what must be included in a PAA. Much of the following is quoted or summarized from Rule 193.8, with explanatory comments added.⁴ The rule states that at a minimum, the PAA must:

1. “be in writing and signed and dated by the parties to the agreement”
2. “state the name, address, and all professional license numbers of the parties to the agreement”
3. “state the nature of the practice, practice locations, or practice settings”
4. “identify the types or categories of drugs or devices that may be prescribed, or the types or categories of drugs or devices that may not be prescribed”

(Note: this section requires that the physician provide detailed guidance to the midlevel professional about which classes of drugs may be prescribed without specific consultation with the physician.

An example for a primary care practice might be to specify various categories of first-line hypertension or asthma medications that can be prescribed by the midlevel, but to state that the physician must be consulted if escalation to other...
drugs is necessary. The new legislation has clarified that physicians can delegate the authority to midlevels to order “durable medical equipment.” (http://www.tmb.state.tx.us/prescriptive-authority-faqs.php)

5. “provide a general plan for addressing consultation and referral”
   (Note: the PAA should address the general circumstances and means by which consultation with the supervising physician will be sought, as well as addressing the general parameters for the discretion to be exercised by the midlevel professionals in making referrals to outside physicians.)

6. “provide a plan for addressing patient emergencies”

7. describe the general process for communication related to the care and treatment of patients
   (Note: you should describe a systematic approach to conveying information to the physician on an as-needed basis, such as through a messaging feature of the EHR. If email is to be used, be sure it is encrypted.)

8. “if alternate physician supervision is to be utilized, designate one or more alternate physicians who may:
   • provide appropriate supervision on a temporary basis in accordance with the requirements established by the PAA and this subchapter; and
   • participate in the prescriptive authority quality assurance and improvement plan meetings required under this section”
   (Note: alternate supervisors should agree and sign the PAA. Also see subsection 12 below. Certain aspects of Rule 185.33 are inconsistent with Rule 193 regarding alternates. I believe the Medical Board will consider it to be acceptable to comply with Rule 193 rather than Rule 185 in this regard.)

9. “describe a prescriptive authority quality assurance and improvement plan and specify methods for documenting the implementation of the plan that includes:
   • chart review, with the number of charts to be reviewed (determined by you); and
   • periodic face-to-face meetings”

10. The face-to-face meetings must include:
   • the sharing of information relating to patient treatment and care, needed changes in patient care plans, and issues relating to referrals;
   • discussion of patient care improvement;
   • documentation of the meetings.

11. The periodic face-to-face meetings shall occur as follows:
   • If the midlevel was not prescribing for at least 5 out of the last 7 years, then monthly for the first 3 years, and quarterly after that, with monthly meetings held between the quarterly meetings via phone or internet.
   • If the midlevel was prescribing for at least 5 out of the last 7 years, but the agreement is not being entered into with the same supervising physician who supervised during the five year period, then monthly for the first year, and quarterly after that, with monthly meetings held between the quarterly meetings via phone or internet.
   • If the midlevel was prescribing for at least 5 out of the last 7 years, and the agreement is being entered into with the same supervising physician who supervised during the five year period, then monthly for the first year, and quarterly after that, with monthly meetings held between the quarterly meetings via phone or internet.

12. “The prescriptive authority agreement may include other provisions agreed to by the physician and advanced practice registered nurse or physician assistant.”

13. If the parties to the PAA are in a group practice, the physician may appoint an alternate to conduct the QA meetings.
   (Note: the alternate should sign the PAA. A group practice is one that is owned and operated by at least two physicians, or is a clinic of a nonprofit health organization. Rule 193.2(12))

14. “The PAA need not describe the exact steps that an advanced practice registered nurse or physician assistant must take with respect to each specific condition, disease, or symptom.”
   (Note: the implication is that the PAA will address a broader range of responsibilities than simply prescribing drugs. The implication appears to be that PAAs will address the work up and assessment
of various medical conditions in addition to prescribing.)
15. Keep the PAA for two years.
16. You cannot agree to nullify the law.
17. If you are being investigated or sanctioned by your disciplinary board, you must tell each other.
   (Note: before entering into a PAA, the physician and the midlevel professional must disclose to each other any prior board action that has ever been taken against them. If, during the pendency of an agreement, either the physician or the midlevel were sanctioned and restricted by their own board from being a party to a PAA, then the PAA would have to be immediately terminated.)
18. The PAA must be reviewed and signed annually.9

You need more than a prescriptive authority agreement (PAA)

Regardless of the seeming ambiguity of the new rules, a PAA only governs prescribing by midlevels. Physicians must still use “protocols” or “standing delegation orders” to delineate further delegation of services and responsibilities. Alternatively, a PAA and the required “protocols” or “standing delegation orders” can be combined into a single document.

TMB rules remain clear that physicians are not to allow the exercise of independent medical judgment by midlevel professionals. A violation of this rule can subject a physician to loss of their license.

The new rules continue to provide for the use of “protocols,” which are defined, in part, as written authorizations delegating the authority to initiate medical aspects of patient care. As noted above, PAAs by their terms only apply to delegation of the authority to prescribe medications and devices.

The new rules make very clear that PAAs are to be distinguished from “protocols” and “standing delegation orders.” This distinction provides a strong indication that the delegation of authority to undertake the medical aspects of patient care, such as by examining the patient, establishing working diagnoses, ordering tests, and making referrals still requires the use of some type of documentary delegation instrument in addition to the basic requirements of a PAA as set out above.

Here is an example that illustrates why some type of delegation instrument is necessary in addition to a PAA.

A patient comes into the clinic with new onset chest pain. He is assessed by a midlevel professional who decides the pain is musculoskeletal. The patient is sent home without a prescription.

Because no prescribing occurred, the PAA has not come into play. Should the midlevel professional have unfettered discretion to assess the patient and decide on a course of action? Or would the TMB expect to see some type of documented delegation of authority that provides general guidance to the midlevel about the handling of potentially complex and potentially fatal medical conditions?

The answer is likely to be the latter given that the TMB has clarified that protocols are distinguished from PAAs, that protocols are the tool used to delegate the authority to initiate the medical aspects of care, and that the TMB expects physicians to specifically document such delegation.

The rules are clear that the specific actions taken by a midlevel professional with regard to each medical condition do not have to be detailed in a delegation document. However, the rules are equally clear that the TMB wants to read a written delegation document that demonstrates that the physician and the midlevel are on the same page in terms of their general understanding of how their most frequently encountered conditions will generally be handled and what “thresholds” or “triggers” should cause the midlevel to promptly involve the physician in the patient’s care.

Very importantly, the TMB recently published FAQs about the new rules:

"Do I need to have a protocol in addition to a prescriptive authority agreement? APRNs and PAs are required to have delegated authority to provide medical aspects of patient care. Historically, this delegation has occurred through a protocol or other written authorization. Rather than have two documents, this delegation can now be included in a prescriptive authority agreement if both parties agree to do so."9

The thrust of this comment by the TMB is that the entirety of the delegation of authority may be included in a single document if you choose to do it that way. But, however you choose to do it, you must document your delegation of both prescribing authority and the authority to undertake other medical aspects of care.

The bottom line is that if you use a PAA that only discusses prescribing, then you need to have a separate document that delegates the authority to undertake the other medical aspects
of care. Alternatively, you may combine both of those separate aspects of delegation into a separate document.

**Practice tip:** For each of the 20 most frequently encountered medical conditions in your clinic, draft a protocol that lists 5 questions that should be considered by the midlevel professional, list the “expected” or “stable” range of findings which are within the realm of the midlevel to treat, list the range of treatments or actions which are usually appropriate (for example, x-ray, usual course of antibiotics, adjust and continue the usual medication regimen, etc.), and list in general terms what would make a patient enough of an outlier that the physician should be consulted promptly.

Even though this exercise may barely scratch the surface of describing all of the situations a midlevel will encounter in actual practice, it demonstrates a thoughtful effort to comply with the spirit of the TMB rules, which is to provide documentation of thoughtful delegation.

**Delegation of controlled substance prescribing**
The general rule about midlevel professionals prescribing controlled substances is a carry-over of the old rule that midlevels may prescribe controlled substances except for Schedule II drugs (Schedule II includes drugs such as hydromorphone, oxycodone, morphine, amphetamine and dextroamphetamine).

Also carried over is the rule that a midlevel professional can prescribe a refill of a Schedule III, IV, or V drug, but only after specific and documented consultation with the supervising physician.

So, while midlevel professionals can initially prescribe these drugs, they cannot prescribe a refill without consulting the physician first. The same pre-approval rule applies to a midlevel prescribing any controlled substance to a child under two years of age.¹⁰

Finally, the prescription and refills can only be for a period not to exceed 90 days.¹⁰ Note that with regard to APRNs, the Board of Nursing’s Rule 222.8 makes clear that this “refill consultation” rule cannot be circumvented by writing a new prescription rather than a “refill.” Additionally, the Board of Nursing’s new Rule 222.3 requires an APRN who prescribes controlled substances to complete three additional contact hours of continuing education related to prescribing controlled substances each biennium.¹¹

Under the TMB’s new rule, prescribing Schedule II drugs can be delegated to midlevel professionals, but only 1) in a hospital-based practice, in accordance with policies approved by the hospital’s medical staff or a committee of the hospital’s medical staff, as provided by the hospital bylaws, for a patient who has been admitted to the hospital for an intended length of stay of 24 hours or greater or who is receiving services in the emergency department, or 2) as part of the plan of care for the treatment of a person who has executed a written certification of a terminal illness, has elected to receive hospice care, and is receiving hospice treatment from a qualified hospice provider.¹²

Remember that for situations in which the professional is not “hospital-based” — such as a surgeon’s midlevel making rounds on patients or a midlevel seeing patients for an outside internist — these midlevels are not allowed to prescribe Schedule II drugs even if the patient has been admitted to the hospital.

Under circumstances in which physicians will be signing controlled substance prescriptions themselves, they must never pre-sign the prescription form for later completion by someone else.¹²

Midlevel professionals who are writing prescriptions for controlled substances must include their own DEA number, and the name, address, phone number, and DEA number for the delegating physician on the prescription.¹³

Midlevels who are providing obstetrical services may “administer or provide” Schedule II drugs, but may not issue a prescription form to the patient for a Schedule II drug.¹⁴

CRNAs are an exception to the Schedule II restriction. CRNAs are allowed to order and administer the drugs needed to perform proper anesthesia in a hospital or ambulatory surgical center. They are also allowed broad discretion with very little specific delegation required of them.¹⁵

**NONSURGICAL MEDICAL COSMETIC PROCEDURES (MEDSPA PROCEDURES)**
The new Rule 193.17 related to treating patients in medspas has imposed very significant new requirements on physicians associated with these practices.¹⁶ Unfortunately, the language of this relatively brief rule presents the practitioner with serious challenges in figuring out exactly which medical situations the rule is intended to cover.

This rule applies to the performance or delegation of nonsurgical medical cosmetic procedures, which are defined as “including but not limited to the injection of medication or substances for cosmetic purposes, the administration of colonic irrigations, and the use of a prescription medical device for cosmetic purposes.”
This rule does not apply to:
1. surgery (as defined by HCFA coding regulations);
2. the practice of a profession by a licensed health care professional under methods or means within the scope of practice permitted by such license;
3. the use of nonprescription devices;
4. intravenous therapy;
5. procedures performed at a physician’s practice by the physician or midlevel practitioners acting under the physician’s supervision; or
6. laser hair removal procedures performed in accordance with Texas Health and Safety Code, Chapter 401, Subchapter M.

So what does the rule apply to? It apparently does not apply to performance of procedures that are within your scope of practice as a physician. Logic would dictate that if a cosmetic procedure can legally be performed by a physician under any circumstances, then the performance of that procedure is necessarily “within the scope of practice permitted by the physician’s license.”

The rule does not apply to procedures that you or your midlevel professional personally perform at a physician’s practice. The rule does not specify how much of your time needs to be spent at this particular clinic location in order for it to qualify as being “at a physician’s practice.” However, it can be safely assumed that this exemption would at least apply to your primary office where you spend the majority of your professional time.

It may be prudent to take the new rule as a very strong suggestion from the TMB about how they think a cosmetic procedure practice (medspa) should be managed. In other words, the text of the new rule is going to be used by the TMB as the de facto standard of care for nonsurgical cosmetic procedures.

When does the new rule apply? A common scenario, which the TMB appears to be targeting, is the freestanding medspa staffed by technicians or nurses at a location completely separate from a physician’s clinic, for which a remotely-located physician is the “medical director.” The TMB’s apparent intent is to drastically change the way these medspas operate. The rule will also affect a physician who uses a nurse or other staff member to perform any of these procedures within their primary practice as an “added service” to patients.

Under the new rule, either a physician or a midlevel professional must examine and assess all patients prior to a procedure. The new rule does not distinguish between a series of procedures and “a procedure.” While it would seem reasonable that a single assessment and prescription for a series of treatments would be sufficient, the TMB has not made a statement about whether this would be adequate.

The following is a slightly summarized version of the details of the rule [with italicized editorial comments]:

1. A physician must be appropriately trained, including hands-on training, in a procedure prior to performing the procedure or delegating the performance of a procedure. The physician must keep a record of his or her training in the office and have it available for review upon request by a patient or a representative of the Board.

2. Prior to authorizing a procedure, a physician, or a midlevel professional acting under the delegation of a physician, must:
   A. take a history;
   B. perform an appropriate physical examination;
   C. make an appropriate diagnosis;
   D. recommend appropriate treatment;
   E. develop a detailed and written treatment plan;
   F. obtain the patient’s written informed consent;
   G. provide instructions for emergency and follow-up care;
   H. prepare and maintain an appropriate medical record;
   I. have signed and dated written protocols as described in paragraph (?) of this subsection that are detailed to a level of specificity that the person performing the procedure may readily follow;
   J. have signed and dated written standing orders; and
   K. [document all of the above].

3. After a patient has been evaluated and diagnosed, qualified unlicensed personnel may perform a procedure only if:
   A. a physician or midlevel practitioner is onsite during the procedure; or
   B. a delegating physician is available for emergency consultation in the event of an adverse outcome, and if the physician considers it necessary, be able to conduct an emergency appointment with the patient. [In other words, at a minimum, the physician must be available to see the patient on
an emergency basis during and shortly after the procedure.]

4. [The physician is ultimately responsible for the procedure and the patient’s safety.]  

5. [The physician is responsible for ensuring proper documentation and for timely co-signing all charts.]  

6. [You must have a documented quality assurance program that includes:]  
   A. identifying complications and adverse effects and to determine their cause;  
   B. reviewing adherence to written protocols;  
   C. monitoring the quality of treatments;  
   D. incorporating findings into future protocols; and  
   E. ongoing training to maintain and improve quality.  

7. A physician may delegate procedures only at a facility in which the physician has:  
   A. approved in writing the facility’s written protocols pertaining to the procedures; or  
   B. developed his own protocols.  

8. The physician must ensure that a person performing a procedure has appropriate training in, at a minimum:  
   A. techniques for each procedure;  
   B. cosmetic or cutaneous medicine;  
   C. indications and contraindications for each procedure;  
   D. pre-procedural and post-procedural care;  
   E. recognition and acute management of potential complications that may result from the procedure; and  
   F. infectious disease control involved with each treatment.  

9. The physician must have a written protocol for performing the procedure that must include:  
   A. the identity of the physician responsible for the procedure;  
   B. selection criteria for the physician or midlevel professional to screen patients for the appropriateness of treatment;  
   C. a description of appropriate care and follow up for common complications, serious injury, or emergencies;  
   D. a statement of the activities, decision criteria, and plan the physician or midlevel professional shall follow when performing or delegating the performance of a procedure, including the method for documenting decisions made and a plan for communication to the authorizing physician or midlevel professional concerning specific decisions made; and  
   E. a description of what information must be documented by the person performing the procedure.  

10. The physician must ensure that the protocols are followed.  

11. Each patient must sign a consent form that lists potential side effects and complications, and the identity and titles of the individual who will perform the procedure.  

12. Each person performing a procedure must be readily identified by a nametag or similar means that clearly delineates the identity and credentials of the person.  

13. Any time a procedure is performed, at least one person trained in basic life support must be onsite.  

**COPIES OF ELECTRONIC MEDICAL RECORDS**  
The Board amended Rule 165.2 regarding the provision of electronic medical records and the fees that can be charged for copies of those records.27  
The amendment states that “If requested, the physician shall provide the requested records in electronic format, if such records are readily producible.” If not, then the rule says to produce them in an agreed-upon format.  
The physician may charge a fee of $25 for 500 or fewer pages of electronic records, and $50 for more than 500 pages. If the records need to be produced partly on paper and partly electronically, then a hybrid fee may be charged that will be a combination of the fee for paper records and the fee for electronic records (in other words, you may charge for both).  

**NOTIFICATION NOT REQUIRED WHEN LOCUM TENENS LEAVE A PRACTICE**  
The amendments to Rule 165.5(f) state that a locum tenens physician who has been at a location for less than six months does not need to notify patients of the discontinuation of their practice.18  
New Rule 165.5(c) states that since the locum tenens is not required to give notice, the new physicians who remain at the practice may prevent the locum tenens from posting a notice of departure in the office and may withhold information from the locum tenens that might have been used to provide notice to patients of the departure of the locum tenens.18
OFFICE-BASED ANESTHESIA

The new amendment to TMB Rule 192 requires any physician using local anesthetics or peripheral nerve blocks in a total dosage that is more than 50% of the recommended maximum safe dosage per outpatient visit to register as an office-based anesthesia provider.19

Another amendment was added to exempt Mohs micrographic surgery from the entirety of Rule 192.

PAIN MANAGEMENT CLINICS

Many changes were made to Rule 195 relating to pain management clinics. These changes are too numerous and too technical to describe here. If you operate a pain management clinic, you are encouraged to study the new rule in full.20

CONCLUSION

With its mission to protect the public and ensure a sufficiently trained physician workforce, the TMB is poised to enforce all rules for which it has responsibility. The practice of medicine is highly regulated and each licensed physician needs to be aware of current TMB guidelines and rules.*

Sources


Dan Ballard can be reached at danballard@ballardsimmons.com.
HIPAA: Clear and present danger for physician practices

by Sarah Churchill Llamas, JD

From the time that HIPAA was enacted in 2003 until the end of 2011, physician practices had little reason to worry about HIPAA security and privacy issues — only one practice was issued a monetary penalty during that time. However, the U.S. Department of Health and Human Services (HHS) received heavy criticism from the Senate in November 2011 for not adequately enforcing the HIPAA regulations. This resulted in settlements totaling more than $1.5 million over the next six months.

This pattern continued with a steady stream of enforcement actions. In addition to investigations resulting from complaints, HHS has begun auditing practices for HIPAA compliance. These audits are intended to encourage physicians to show renewed attention to HIPAA compliance activities.

AUDITS
The American Recovery and Reinvestment Act of 2009, in Section 13411 of the HITECH Act, requires HHS to provide for periodic audits to ensure compliance with HIPAA Privacy and Security Rules and Breach Notification standards. To implement this mandate, the Office for Civil Rights (OCR) piloted the 2012 HIPAA Compliance Audit Program that performed 115 audits. The OCR believes that this program will “spur” covered entities and business associates to “assess and calibrate their privacy and security protections.” In light of this, all HIPAA covered entities should review their HIPAA policies and procedures, conduct a risk assessment, update their Notice of Privacy Practices, and generally ensure they are compliant.

Who is eligible to be audited?
Any covered entity may be audited. The OCR purposely began auditing entities of different types and sizes during the 2012 pilot program. Of the first 20 entities audited, 30% of the audits were of small providers/health plans (10 to 50 provider practices with revenues and/or assets less than $50 million.

At the conclusion of the program, the top HIPAA official said covered entities are failing to complete basic tasks, such as conducting a risk analysis and giving out a notice of privacy practices.

Audits may lead to enforcement actions.
While the OCR has indicated that they intend the audits to serve as a compliance improvement tool, an audit could trigger a separate enforcement investigation by OCR. It is estimated that more than 100 audits were conducted in 2012.

ENFORCEMENT ACTIONS
Failure to comply with HIPAA can result in civil and criminal penalties. The civil penalties can be onerous, especially for small practices and are based on the nature and extent of the violation and resulting harm.
OCR has also launched three modules for physicians on compliance with various aspects of the HIPAA Privacy and Security Rules, available at Medscape.org:

1. Patient Privacy: A Guide for Providers
2. HIPAA and You: Building a Culture of Compliance
3. Examining Compliance with the HIPAA Privacy Rule

Breaches involving laptops or other portable electronic devices have accounted for nearly 40 percent of all breaches affecting 500 or more individuals since 2009. Because of the increasing role portable devices play in health care, OCR has launched a new educational initiative, Mobile Devices: Know the RISKS. Take the Steps. Protect and Secure Health Information, to offer practical tips for protecting patient information when using mobile devices. For more information, please visit www.HealthIT.gov/mobiledevices.

**INSURANCE**

Cyber liability coverage can protect your practice from regulatory fines and penalties resulting from HIPAA security and privacy breaches. Many policies will cover the costs associated with patient notifications and credit monitoring services. TMLT includes cyber liability coverage limits of $50,000 per claim subject to a $50,000 aggregate per policy period, with the option to purchase increased limits up to $1 million. Please visit the TMLT website for more information.*

**Sources**


3. 42 USC § 1320d-5


<table>
<thead>
<tr>
<th>ACTION</th>
<th>MINIMUM PENALTY</th>
<th>MAXIMUM PENALTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person did not know (and by exercising reasonable diligence would not have known) that such person violated HIPAA</td>
<td>$100 per violation, with an annual maximum of $25,000 for repeat violations (Note: this is the maximum that can be imposed by State Attorneys General regardless of the type of violation)</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
</tr>
<tr>
<td>HIPAA violation due to reasonable cause and not to willful neglect</td>
<td>$1,000 per violation, with an annual maximum of $100,000 for repeat violations</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
</tr>
<tr>
<td>HIPAA violation due to willful neglect but violation is corrected within 30 days</td>
<td>$10,000 per violation, with an annual maximum of $250,000 for repeat violations</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
</tr>
<tr>
<td>HIPAA violation is due to willful neglect and is not corrected</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
</tr>
</tbody>
</table>
Negligence in prescribing chemotherapy

by Louise Walling and Laura Hale Brockway, ELS

PRESENTATION

A 56-year-old woman came to a general surgeon on July 9 after her mammogram showed a lesion in the right breast. The surgeon performed a partial mastectomy with right sentinel node excision and partial reconstruction. The patient was referred to an oncologist.

PHYSICIAN ACTION

The oncologist — the defendant in this case — recommended chemotherapy with taxotere 60 mg and cyclophosphamide 600 mg every 3 weeks for six weeks.

Before starting chemotherapy, the oncologist ordered a complete blood count and a complete metabolic panel. The results revealed the patient had an elevated bilirubin of 1.6 (normal 0.2-1.2); elevated alkaline phosphatase of 243 (normal 33-130); elevated AST of 271 (normal 10-35); and an elevated ALT of 60 (normal 6-40). Given the elevated lab values, the oncologist delayed chemotherapy.

Because additional lab work continued to show elevated lab values, the oncologist referred the patient to a gastroenterologist. The gastroenterologist believed the patient’s liver disease was secondary to alcohol consumption. The oncologist hoped to start the patient’s chemotherapy after her liver function test (LFT) values were “close to normal.”

Additional lab work completed on December 11 showed bilirubin of 1.4 (normal 0.2-1.2); alkaline phosphatase of 154 (normal 33-130); AST of 31 (normal 10-35); and ALT of 58 (normal 6-40). The oncologist noted the patient had been seeing the gastroenterologist who confirmed the patient was drinking alcohol.

The patient returned to the oncologist on January 11. She reported that she had stopped drinking alcohol over the last two months. Lab results showed bilirubin of 4.7 (normal 0.2-1.2); alkaline phosphatase of 229 (normal 33-130); elevated AST of 196 (normal 10-35); and an elevated ALT of 49 (normal 6-40).

A note in the chart entered on January 12 stated that the taxotere and cyclophospha-
The patient returned to the oncologist on January 25. She reported that she was feeling fine. The oncologist wrote in the patient’s chart that her bilirubin was tested several weeks ago and had gone up to 4. The patient underwent lab work that day, but no LFTs were ordered. She was sent for her initial dose of chemotherapy.

Six days passed and the patient called the oncologist’s office to report that she had been experiencing weakness for the past five days. She had difficulty walking and was not eating. The patient was told to go to the emergency department (ED).

The patient came to the ED and was admitted to ICU. Her diagnosis was pancytopenia, liver failure, respiratory failure, cirrhosis, and sepsis. Despite her treatment, she was unable to recover. She died on February 1. There was no autopsy performed. The death certificate listed the cause of death as septic shock and multi-system organ failure.

**ALLEGATIONS**

A lawsuit was filed against the oncologist, alleging negligence in prescribing chemotherapy in a patient with an elevated bilirubin level.

**LEGAL IMPLICATIONS**

Physicians who reviewed this case for the defense were critical of the oncologist’s decision to begin chemotherapy in a patient with elevated bilirubin levels, particularly because the oncologist had previously withheld chemotherapy due to the elevated bilirubin, complicated the defense of this physician. Although the patient reported she was feeling “fine,” it was not enough to begin chemotherapy.

During the investigation of this claim, it was discovered that the oncologist’s office had just begun using electronic medical records. The oncologist’s staff may have only seen his original order for chemotherapy and not his notes indicating a discontinuation of the order until the patient’s LFT values were normal.

Importantly, defense consultants believed the chemotherapy drugs directly caused the patient’s liver and respiratory failure.

**DISPOSITION**

This case was settled on behalf of the oncologist.

**RISK MANAGEMENT CONSIDERATIONS**

Negligence means failure to use ordinary care. In this claim, ordinary care means that degree of care an oncologist of ordinary prudence would use under the same or similar circumstances.

Scheduling chemotherapy for a patient without obtaining further liver function studies, after he had previously withheld chemotherapy due to the elevated bilirubin, complicated the defense of this physician. Although the patient reported she was feeling “fine,” it was not enough to begin chemotherapy.

Moving through the transition from paper to electronic records can lead to lapses in communication or medical errors. During this time, physicians are required to be absolutely clear with their orders and staff need to be vigilant in considering any supporting documentation regarding the order.

Louise Walling can be reached at louise-walling@tmlt.org.

This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician’s defensibility. An attempt has been made to make the material less easy to identify. If you recognize your own case, please be assured it is presented solely to emphasize the issues of the case.
**Medication error**

by Louise Walling and Laura Hale Brockway, ELS

**PRESENTATION**

A 79-year-old woman came to the emergency department (ED). She reported nausea, vomiting, and diarrhea for one week. Two months earlier, the patient had experienced gastrointestinal bleeding with anemia and there was concern about recurrent bleeding.

The patient’s medical history included hypertension, asthma, COPD, and anemia. She was also allergic to levofloxacin.

**PHYSICIAN ACTION**

The emergency medicine physician ordered lab work and a CT scan of the abdomen and pelvis. Results from the lab work showed a normal white blood cell count, hemoglobin, and hematocrit. The patient had depleted bicarbonate and elevated creatinine. The CT scan indicated moderate diverticulosis, large hiatal hernia, and mild small bowel distention.

The patient was admitted under the care of a hospitalist. Because the wait for a bed was going to be prolonged, the hospitalist saw the patient in the ED. The hospitalist diagnosed gastritis and began the patient on IV levofloxacin and metronidazole, noting the patient was allergic to dalteparin.

The hospitalist did not review the ED electronic records and she did not see the documentation that the patient was allergic to levofloxacin. Since the medication was dispensed in the ED, it did not go through the same channels as medication dispensed on the floor. The pharmacy did not review the appropriateness of the medication.

Following the administration of levofloxacin, the patient experienced an anaphylactic reaction requiring cardiopulmonary resuscitation, intubation, and admission to the ICU. She died two days later.

**ALLEGATIONS**

A claim was filed against the hospitalist. The claim alleged that had the hospitalist reviewed the records in the ED and had she conducted an appropriate history and physical, she would have learned about the patient’s medication allergy and would not have ordered levofloxacin.
**LEGAL IMPLICATIONS**
In reviewing this case, the hospitalist stated that she could have known the patient was allergic to levofloxacin had she looked at the ED records. She did not remember asking about drug allergies, though she interviewed the patient through one of the patient’s daughters because the patient only spoke Spanish. The hospitalist reported that she prescribed levofloxacin as a prophylactic measure.

Physicians who reviewed this case for the defense questioned why the patient was prescribed antibiotics. She had no fever, was stable, and did not have any studies indicating a need for antibiotics.

It was also noted that the nurse in the ED who dispensed the medication did not check the patient’s record for allergies or ask the patient if she was allergic to any medication.

The medical records did indicate that the hospitalist discussed the medication error with the family and accepted responsibility for the error. She arranged for further consultations and handed over the care of the patient to a colleague when the family requested a new physician.

**DISPOSITION**
This case was settled on behalf of the hospitalist.

**RISK MANAGEMENT CONSIDERATIONS**
Due to a shortage of hospital beds, the admitting physician evaluated the patient and initiated treatment in the ED. Instead of consulting the ED records, she reviewed previous medical records that did not provide accurate information. Reviewing the accessible and most current ED records would have given the physician the information she needed to proceed.

The patient’s allergies were correctly reported since that information was documented in the ED record. Obtaining a thorough medical history from a patient is the optimal way to collect pertinent health information. There is no substitute for a good basic history in which the physician asks the patient about allergies to medications and documents the conversation. If information is taken from old medical records, current patient history needs to state if any new or additional allergies are present.

Medication errors usually have multiple complex factors and can be prevented at various levels. In the case, the RN hanging the infusion with the levofloxacin had a responsibility to ask about allergies and double check for accurate information.

Louise Walling can be reached at louise-walling@tmlt.org.

This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician’s defensibility. An attempt has been made to make the material less easy to identify. If you recognize your own case, please be assured it is presented solely to emphasize the issues of the case.