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"When will our consciences grow so tender that we will act to prevent human misery rather than avenge it?"

— *Eleanor Roosevelt*

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MESSAGE FROM THE CHAIR

IT IS TIME TO LEAD

Martin Crane, M.D., Chair, Federation of State Medical Boards

It is, indeed, a privilege to serve as the new chair of the Federation of State Medical Boards' board of directors. The FSMB was formed in 1912, and on July 26, 1913, an editorial in *Harper's Weekly* commented, "There should be a hearty welcome from the entire public to the newly formed Federation of State Medical Boards. It not merely aims at an end indisputably desirable, but it seems a feasible and practical plan to accomplish that end." What "end" were they noting? They were referring to the function of state medical boards, in their words: "to decide upon the qualifications to be required to practice medicine and that none do practice without the fixed minimum of knowledge and experience."

Nearly a century later, the words may have changed and our qualification and assessment methods may be more sophisticated, but our compact with the public is the same: to protect the public and ensure, for the sake of the public as well as the medical profession, only qualified and competent physicians are given the right to practice. For us to continue to fulfill our responsibility to the public we must focus on the core aspects of our organization that provide the best opportunity to carry out our mission and allow us to remain viable, exercise leadership and collaborate with others. This also means being always nimble and ready to react to change in a positive and determined manner.

We are confronted with significant challenges in maintenance of licensure, reentry to practice, scope of practice issues and a more proactive role for state medical boards in correcting and preventing — rather than reacting to — today's health care problems. The FSMB accepts the challenge and the opportunity to be both a leader and a partner in networking the diverse, unique and exceptional resources of all stakeholders in a collaborative effort to address these challenges in the best interests of the public and the medical profession.

At its heart, the FSMB remains a membership organization. The primary role of the FSMB is to support the state boards in their vital work and to represent the needs, goals, successes and challenges of state boards in national policy forums concerned with health care regulation and reform, patient safety and ensuring access to the highest quality health care. Patients rely on their state boards to protect them, and this can only occur when those boards are well funded, have appropriate resources and are statutorily strong.

We must commit ourselves to promoting the recognition of the FSMB and the new FSMB Foundation as leaders and public resources for patient safety and patient protection. The FSMB and the Foundation, in partnership, must strengthen their support to member boards as they develop new and innovative approaches to improve health care quality and reduce patient harm, while also assisting physicians in continuing to improve the quality of their practices. Tools to accomplish this include more regular, interactive dialogue with and among our member boards; increased use of technology for enhanced data collection, dissemination and analysis; and such programs as credentialing and license portability. All will synergistically assist all boards in serving the public and the medical profession.

In this dynamic world of health care and impending reform, we must win the trust and confidence of the public and physicians — literally their hearts and their minds — and convince them we can do our job efficiently, effectively and fairly. We ask everyone to join with us in this endeavor and work toward a worthy, shared goal: access to the highest quality care for all patients, practiced by the most competent and dedicated health care professionals.

As Mark Twain once said: "Always do what is right. This will gratify some people, and astound the rest." Together we can do a great deal of astounding.

EDITORIAL

USE OF THE DOCTOR TITLE IN CLINICAL SETTINGS

Robert S. Crausman, M.D., M.M.S., Bruce McIntyre, J.D.

The clinical title of "doctor" was, for many years, synonymous with physician. However, this is no longer true. A number of clinical disciplines have moved towards doctorate-level training as a requirement for clinical practice and licensure. Clinical psychologists, chiropractic physicians, optometrists and pharmacists are doctorate-level providers. Currently, nurse practitioner and anesthetist programs and physical therapy programs also are moving in this direction.

In each case it has been argued that these increasing levels of training are necessary, given the increasing complexity of medical practice. Others have cogently asserted that such requirements are simply a heightened barrier to limit entry into the field with adverse economic consequences to the cost of health care. Regardless, it is clear there is a proliferation of nonphysician "doctors" in the clinical environment. The potential confusion to patients is compounded by the quiet displacement of physicians in primary care settings by advanced practice clinicians.

Recently resolutions 211 and 232 of the American Medical Association House of Delegates asserted (1) that confusion, injury and a breakdown of quality medical care would result from persons not trained as medical doctors and doctors of osteopathy misrepresenting themselves as doctors in clinical settings, (2) that the quality of care rendered by individuals with the nurse doctoral degree is not equivalent to that of a physician and (3) that nurses and other nonphysician providers who hold doctoral degrees and identify themselves to patients as doctors will create confusion, jeopardize patient safety and erode the trust inherent in the true patient-physician relationship. In so doing they resolved to pursue a course of action to counter such misrepresentation by nurse doctoral programs, their students and graduates.[1,2] Additionally, by 2007 seven states had statutes or regulations prohibiting a nurse practitioner from using the "doctor" title.[3]

Clearly this is a topic fraught with passion and controversy. With prior similar such controversies as the legitimacy of chiropractic medical practice, the role of physicians in the debate was often seen as protectionist and imbalanced. It will be regrettable if this historical pattern is repeated.

Health care professionals who earn a doctorate in a recognized field of scholarly and clinical endeavor merit the title "doctor." At the same time there must be clear and effective safeguards in place to protect patients and to assure appropriate disclosure of credentials and training. At a minimum printed materials such as letterhead, business cards and brochures should be unambiguous. Labeling of white coats and ID badges similarly should be forthright. Guidelines for appropriate advertising also should be adopted.

The practice by some states of appending the title doctor to license types below the doctorate level must be discontinued. For example, licensure of an acupuncturist in the state of Rhode Island[4] does not require doctoral level training but the license designation is "Doctor of Acupuncture." Similarly, honorary titles, even when awarded by academic institutions, have no place in clinical settings. The title "doctor" may not be synonymous with physician but it must connote achievement of an actual doctorate in a recognized clinical discipline.

State medical and nursing boards have the obligation to speak authoritatively and introduce balance and reasonableness into what must be a national dialogue. The Federation of State Medical Boards has the opportunity to foster the development of a uniform national standard through the development of model guidelines with collaboration from other stakeholder groups.

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DOES THE EMPLOYMENT OF PHYSICIAN ASSISTANTS AND NURSE PRACTITIONERS INCREASE LIABILITY?

Roderick S. Hooker, Ph.D., PA, Jeffrey G. Nicholson, Ph.D., PA, Tuan Le, M.D., DrPH

ABSTRACT

We assessed whether physician assistant (PA) and nurse practitioner (NP) utilization increases liability. In total, 17 years of data compiled in the United States National Practitioner Data Bank (NPDB) was used to compare and analyze malpractice incidence, payment amount and other measures of liability among doctors, PAs and advanced practice nurses (APNs).

From 1991 through 2007, 324,285 NPDB entries were logged, involving 273,693 providers of interest. Significant differences were found in liability reports among doctors, PAs and APNs. Physicians made, on average, malpractice payments twice that of PAs but less than that of APNs. During the study period the probability of making a malpractice payment was 12 times less for PAs and 24 times less for APNs. For all three providers, missed diagnosis was the leading reason for malpractice report, and female providers incurred higher payments than males. Trend analysis suggests that the rate of malpractice payments for physicians, PAs and APNs has been steady and consistent with the growth in the number of providers.

There were no observations or trends to suggest that PAs and APNs increase liability. If anything, they may decrease the rate of reporting malpractice and adverse events. From a policy standpoint, it appears that the incorporation of PAs and APNs into American society has been a safe and beneficial undertaking, at least when compared to doctors.

INTRODUCTION

Physician assistants (PAs) and nurse practitioners (NPs) were introduced in the United States health care system to improve the delivery of health care services and assist the overburdened primary care doctor.[12] This was considered a medical experiment at the time as a means to extend health care services to a growing population. During four decades, a series of federal policies has ensconced the PA and NP in American society; they are considered effective in the services they provide, and patient satisfaction does not appear to differ from that of physicians.[13] They are located throughout the American system and in all roles traditionally occupied by physicians, often at higher levels in underserved locations.[11] Patients and other health care providers nationwide recognize PAs and NPs. They are licensed to practice and prescribe in all states, and receive compensation for their services through Medicare, Medicaid and most all insurance companies. Yet little is known about disciplinary actions and malpractice claims when patients are injured by PAs and NPs.

The nurse role has evolved into a spectrum of providers: NPs, clinical nurse specialists (CNSs), certified nurse midwives (CNMs) and certified registered nurse anesthetists (CRNAs). Collectively these semi-autonomous nurses are known as advance practice nurses (APNs). PAs and APNs are often counted as a body of health care workers that provide clinical services traditionally provided only by doctors.[12] We set out to investigate if PAs and NPs negate any of their cost effectiveness by examining a national registry of malpractice and adverse action reports.

Only a few studies have examined whether PA/NPs invoke liability differently than doctors.[3,4,10] All studies concluded that the liability of an NP or PA was less than that of a doctor in terms of malpractice payments or number of citations. The source of data for these small studies, undertaken in the early 1990s, was the nascent National Practitioner Data Bank (NPDB). Since the inception of the NPDB in 1990, a great deal of experience and data has accumulated. According to the NPDB 2005 Annual Report:

Less than one percent of all medical malpractice pay-

ment reports are related to PAs. Among medical malpractice, diagnosis-related problems and treatment-related payments were the greatest. The second largest payments, both cumulatively and in 2005, were due to PAs. Approximately 2 percent of malpractice payment reports were for professional nurses. Most of them related to monitoring, treatment and medication problems; proportions of payments were 61.9 percent for non-specialized registered nurses, 20.0 percent for nurse anesthetists, 9.3 percent for nurse midwives, and 8.8 percent for nurse practitioners. The ratio of nurse payment reports to physician payment reports varied from 0.02 percent in Vermont to 9.0 percent in Alabama.

The National Practitioner Data Bank

The National Practitioner Data Bank (NPDB) was established under Title IV of Public Law 99-660 of the Health Care Quality Improvement Act of 1986. It receives federally required reports of malpractice payments and adverse actions on heath care practitioners. This federal registry has recorded actions reported on physicians, dentists, pharmacists and other licensed health care practitioners in the United States since September 1990. Medicaid and Medicare "exclusions" were included in 1997. These include actions wherein a provider was found guilty of a malpractice claim and was excluded from filing for reimbursement from the federal government for further health care of patients. Adverse actions can involve licensure, clinical privileges, professional society membership and exclusions from Medicare and Medicaid participation. Reports can involve health care-related criminal convictions, civil judgments and other adjudicated actions or by any civil or criminal court system. Malpractice refers to misconduct, unprofessional conduct, mismanagement or negligence. Liability refers to legal responsibility, accountability responsibility or charge.

As of January 2008, the NPDB data consists of more than 414,404 cases and 51 variables, including information about characteristics of health care practitioners with medical malpractice payments and adverse actions. The list of actions includes license actions, clinical privileges actions, professional society membership actions, Drug Enforcement Administration (DEA) actions and Medicaid/Medicare program exclusions. Four report types were reclassified into adverse action reports, consisting of data with format used before and after November 1999, and malpractice payment, consisting of data with format used before and after January 2004.

Health care providers in this study were selected and reclassified into three types: (1) physicians, including allopathic physicians (MD/MBBS), osteopathic physicians (DOs) and physician interns/residents; (2) PAs; and (3) APNs. The number of active physicians was obtained from the *Physician Characteristics and Distribution in the U.S.*, 2008 edition, a report published by the American Medical Association (AMA). The number of PAs was obtained from the American Academy of Physician Assistants Information Update.[1,2] The number of APNs was obtained from the National Nursing Survey Report (NSSR) of the U.S. Health Resources and Services Administration.[6,7] NNSR data includes both active and non-active APNs. The number of APNs is known only generally because there is no centralized registry of graduates and clinically active nurses.

METHOD

The NPDB maintains a website with data available for downloading.[5] *Data recorded from 1 January 1991 through 31 December 2007*, were identified for analysis. Independent variables were PAs, APNs and doctors (MD, DO, MBBS). Dependent variables included medical malpractice payment incidence, payment amount, ratios of payments to provider type, state licensure and professional society membership actions, federal program exclusions, age and time-in-practice of provider and patient and provider gender. Compensation for damages includes averages (mean and median) of payments, total of payments (current value of dollars in millions) and total amount of payments (which was adjusted for inflation). For comparison purposes, all payments were changed to 2008 dollars using the percent inflation for each year based on a calculated formula from the Consumer Price Indexes of the U.S. Department of Labor, Bureau of Labor Statistics (BLS).[8] Data for active physicians was taken from *Physician Characteristics and Distribution in the U.S.*, 2008 edition, American Medical Association (received from the Data Coordinator, Survey & Data Resources, American Medical Association: personal communication, AMA, 14 May 2008). Data for active PAs was obtained from the *American Academy of Physician Assistants Information Update.*[1,2] Data for APNs was derived from the National Nursing Survey Reports (NNSR) of the U.S. Health Resources and Services Administration.[6,7] NNSR data includes both active and non-active APNs. Nonparametric statistics include Chi-square and Sheffe's method of one-way ANOVA for comparison among three types of health care providers.

RESULTS

Spanning 17 years (01 January 1991 through 31 December 2007) the NPDB recorded 324,285 total entries for the three

providers of interest: doctors, PAs and APNs. The number of physician reports was 320,034 while the number of PA reports was 1,535 and APN reports were 2,715 (Table 1). A total of 273,693 providers were involved (a few providers had multiple reports).

The mean age of physicians, PAs and APNs at the time of an event leading to the report entered in the NPDB were 43 (±11), 37 (±9) and 41 (±11) years, respectively (Table 2). For adverse action reports, the mean age of doctors, PAs and APNs at the time of adverse action leading to report was 48 (±11), 41(±9) and 43 (±9) years, respectively.

The top five reasons for malpractice payments among physicians were diagnosis (33.9 percent), surgery (27.1 percent), treatment (18.0 percent), obstetrics (8.6 percent) and medication (5.5 percent). The top five reasons among PAs were diagnosis (55.5 percent), treatment (24.6 percent), medication (8.5 percent), surgery (4.6 percent) and miscellaneous (3.1 percent). For APNs, the top five reasons for payments were anesthesia (38.7 percent), obstetrics (22.2 percent), diagnosis (14.8 percent), treatment (10.5 percent) and medication (4.8 percent). A chi-square test shows a significant association between reasons for malpractice payment and type of health care provider (χ^2 =11525.38 and p<0.0001). In the aggregate, for the same

Table 1.

National Practitioner Databank Entries by Provider Type: 1991 – 2007

		Malpractice Reports		
Type of Provider	Total Entries	Number of Malpractice Payments	Number of Adverse Actions Reported	Number of Involved Providers
Physician	320,034	245,267	74,767	268,919
PA	1,536	1,222	314	1,509
APN	2,715	2,608	107	3,265
Total	324,285	249,097	75,188	273,693

Total entries: χ^2 = 576.67; df =2; p< 0.0001; effective sample size n= 324,285.
Malpractice Payment field: χ^2 = 181.36; df =2; p< 0.0001.
Adverse action field: χ^2 = 565.66; df =2; p< 0.0001.

Table 2.

Provider Characteristics: National Practitioner Databank 1991 – 2008

	Reports by Provider			Mean Age (years) at Time of Event Leading to Report	
Provider	Number of Reports	Average Number of Providers per Report	Number of Providers	Adverse Action*	Malpractice‡
Physician	320,034	1.10	268,919	48 (±11)	43 (±11)
PA	1,536	1.24	1,509	41 (± 9)	37 (± 9)
APN	2,715	1.26	3,265	43 (± 9)	41 (± 9)

‡F=280.19 and p<0.0001
*** F=65.44 and p<0.0001**
± Standard Deviation

reporting period, physicians totaled 245,153 medical malpractice payments while PAs had 1,222 payments and APNs had 2,608. The leading category of reason for medical practice payment for physicians (83,130 of 245,153) and PAs (678 of 1,222) was diagnosis error.

Malpractice payments for all of the study years for all providers exceeded $74 billion. PA payments comprised just 0.003 percent of the total; APN payments comprised only 0.007 percent of the total. Mean and median payments, for each provider were: APNs at $350,540 and $190,898; physicians at $301,150 and $150,821; PAs at $173,128 and $80,003. The adjusted mean payment for doctors was 1.7 times higher than PAs and 0.9 that of APNs. The adjusted median payment for doctors was 1.9 times that of PAs and 0.8 that of APNs. Among providers, the APN adjusted mean payments were 2.0 times that of PAs, and median payments were 2.4 times that of PAs.

The mean malpractice payments by year for the study period for all three provider types adjusted for inflation to 2008 dollars are displayed in Figure 1. Statistical significance was preserved by year. Mean payment amounts increased throughout the study period for all three-provider groups. The mean payment amounts of APNs were higher than that of physicians and PAs.

When the slopes of malpractice payments are compared, physicians have a lower increase in inflation-adjusted payments per year than PAs and APNs. Mean payments for physicians increased by $5,620 per year during the study period while that of PAs increased by $8,993 and APNs by $8,706. Although APN malpractice payments are higher than physicians and PAs, the payment amount rate was parallel to the rate of PAs during the same study period.

Figure 2 displays the mean and median payments for malpractice reports by gender for the full 17-year study period in 2008 dollars. The data reveals that female providers, regardless of clinician type, had larger malpractice payments on average than males when aggregated or by provider (with the median slightly lower for PAs).

Malpractice reports and adverse action reports by year for all three providers are displayed in Table 3. The year with the largest number of physician malpractice reports was 2001. Physician malpractice reports remained fairly consistent between 1991 and 2005, then decreased in 2006 and 2007. PA malpractice reports increased, peaking at 135 in 2004 with a jump from 81 in 2001 to 123 in 2002, but decreased from 2004 to 2007. The number of APN malpractice reports ranged between 90 and 140, but increased from 111 in 2000 to 183 in 2001, and increased

Figure 1. Mean Malpractice Payment by Year from 1991–2008

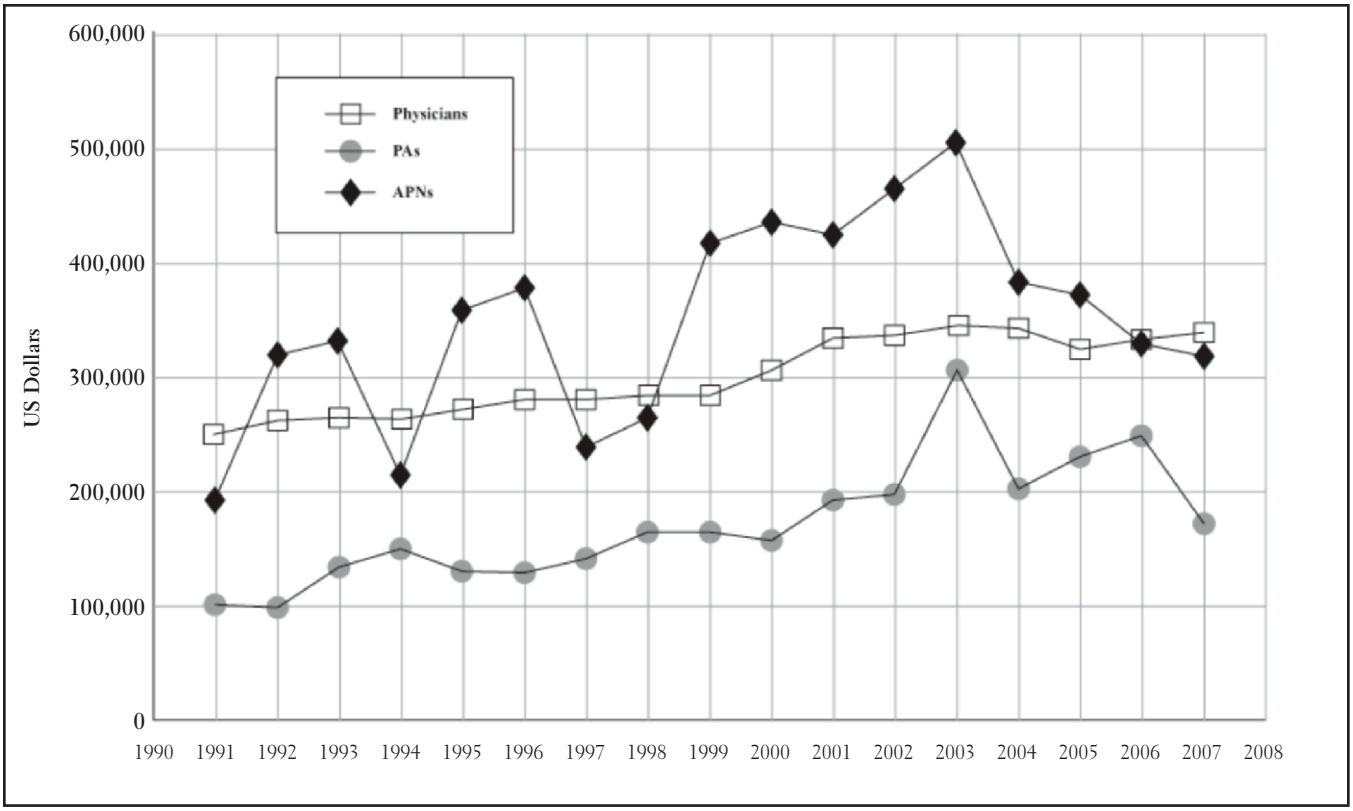
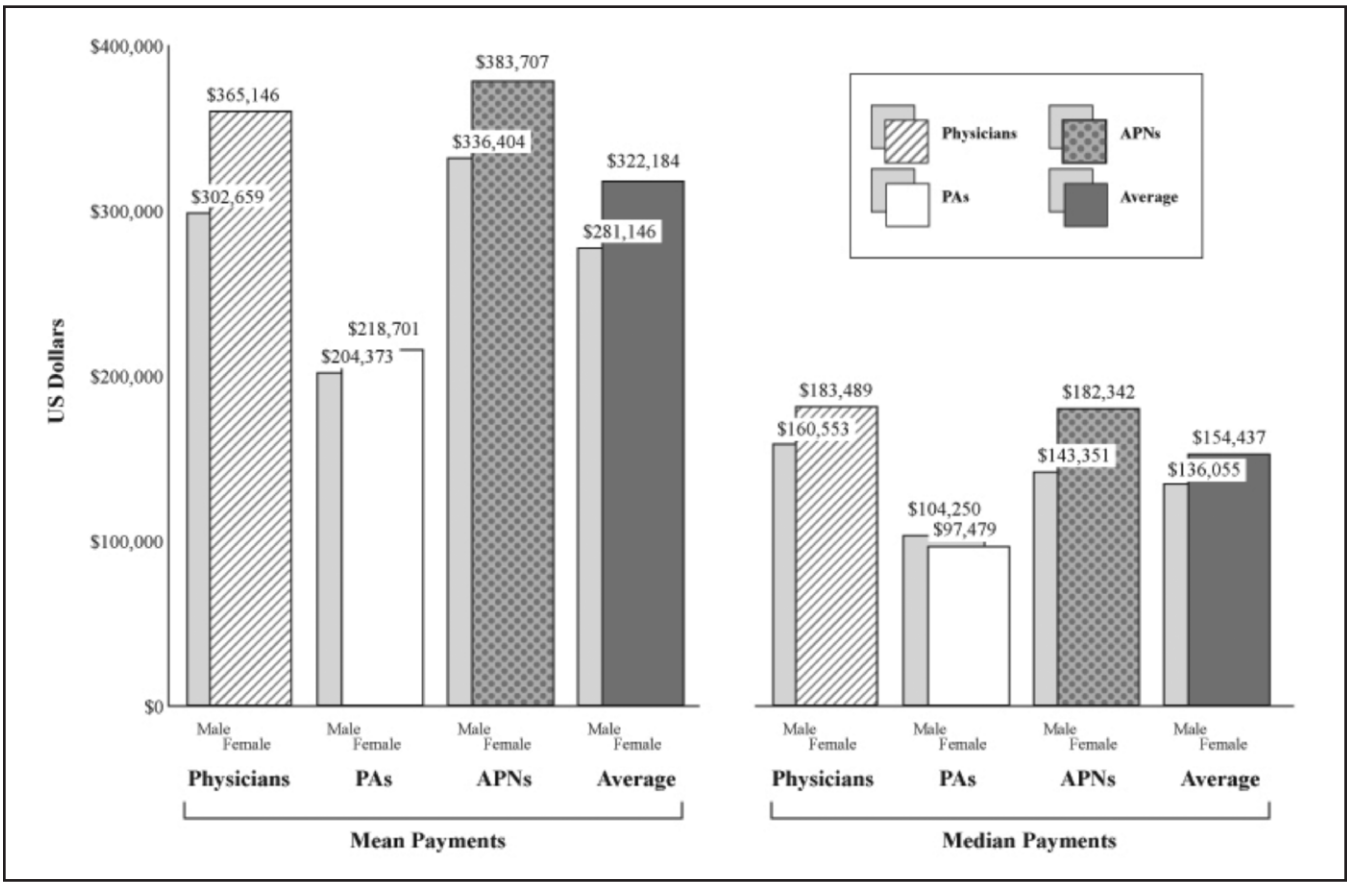


Figure 2. Mean and Median Malpractice Payment by Provider Gender for 1999–2008



again in 2004, 2005 and 2006 (from 168 in 2003 to 264 in 2006). The largest percent change in malpractice reports for physicians was a decrease in 1995 of 11.4 percent; for PAs an increase in 2002 of 51.1 percent; and for APNs an increase in 2001 of 61.3 percent.

The rate and amount of malpractice payments was compared. A ratio of malpractice payments per total number of active providers in 2006 (the most recent year that demographic data was available for all provider groups) for each provider type is displayed in Table 4. There were 12,495 payments for 774,883 physicians, 113 payments for 63,609 PAs and 264 payments for 268,293 APNs. These ratios were 1:62, 1: 563 and 1:1,016, respectively.

The number of malpractice payments during the 17-year period per average number of active providers within the 17-year study period is provided in Table 5. There was one payment report for every 2.7 active physicians, one for every 32.5 active PAs and one for every 65.8 APNs (combined active and non-active). Assuming one malpractice payment per provider, 37 percent of physicians, 3.1 percent of PAs and at least 1.5 percent of APNs would have made a malpractice payment during the 17-year period.

The most common bases for adverse action reports since reporting began (Nov. 22, 1999 to Dec. 31, 2007) are licensing action by federal, state or local licensing authorities. For physicians there were 10,336 events. For PAs there were 107 events and for APNs there was one event.

Medicare and Medicaid are federal health care programs for the elderly and poor. A violation occurs when a practitioner is found guilty of fraud, abuse or some other violation in providing these services and results in an exclusion from these service reimbursements. Exclusions from Medicare and Medicaid programs constituted 9.9 percent of all adverse actions reported. There were 6,311 physicians excluded from Medicare and Medicaid Programs in the study period, or 0.8 percent of the active physician population in 2006, and 219 PA exclusions, or 0.3 percent of the active PA population in 2006. There were no APN exclusions.

Patients' age and gender, stratified by malpractice claims for only the four years available (Jan. 31, 2004, through Dec. 31, 2007) were analyzed (Table 6). There were 47,457 patients involved in malpractice payments by physicians during this period; 26,483 females (55.8 percent) and 20,974 males (44.2 percent). PAs and APNs were involved with less

Table 3.

Number of Malpractice and Adverse Action Reports by Year and Type of Provider			
Year	Provider	Malpractice Payment Report	Adverse Action Report
1991	Total	13,522	3,487
	Physicians	13,399	3,480
	PAs	14	6
	APNs	109	1
1992	Total	14,839	3,570
	Physicians	14,692	3,549
	PAs	30	16
	APNs	117	5
1993	Total	14,771	3,910
	Physicians	14,629	3,896
	PAs	33	11
	APNs	109	3
1994	Total	15,258	4,293
	Physicians	15,124	4,266
	PAs	44	24
	APNs	90	3
1995	Total	14,120	4,692
	Physicians	13,988	4,676
	PAs	39	12
	APNs	93	4
1996	Total	15,336	4,882
	Physicians	15,186	4,873
	PAs	44	8
	APNs	106	1
1997	Total	14,696	4,920
	Physicians	14,531	4,892
	PAs	46	22
	APNs	119	6
1998	Total	14,103	4,998
	Physicians	13,944	4,971
	PAs	49	22
	APNs	110	5
1999	Total	15,151	4,742
	Physicians	14,945	4,720
	PAs	75	20
	APNs	131	2
2000	Total	15,631	4,300
	Physicians	15,447	4,274
	PAs	73	23
	APNs	111	3
2001	Total	16,831	4,504
	Physicians	16,571	4,471
	PAs	81	26
	APNs	179	7
2002	Total	15,506	4,278
	Physicians	15,200	4,251
	PAs	123	22
	APNs	183	5
2003	Total	15,520	4,376
	Physicians	15,233	4,338
	PAs	119	27
	APNs	168	11
2004	Total	14,722	4,484
	Physicians	14,373	4,440
	PAs	135	23
	APNs	214	21
2005	Total	14,380	4,342
	Physicians	14,011	4,319
	PAs	110	12
	APNs	259	11
2006	Total	12,872	4,240
	Physicians	12,495	4,210
	PAs	113	20
	APNs	264	10
2007	Total	11,839	3,744
	Physicians	11,499	3,722
	PAs	94	14
	APNs	246	8

than 2 percent of patients relating to malpractice payments. For PAs, 203 (47.7 percent) female patients and 223 (52.3 percent) male patients were involved in malpractice payment reports. For APNs, 536 (59.2 percent) female patients and 369 (40.8 percent) male patients involved in malpractice payment reports. The chi-square test revealed a significant association between patients' age and gender with the type of care provider ($p<0.0001$ for each provider). For all provider types, the total number of females involved was 27,322 or 56 percent of the total.

DISCUSSION

The NPDB is the nation's repository of reports on liability and adverse actions, including payments, for a spectrum of health care providers. An entry in the NPDB must be a report about a case in which adjudication had been reached and the case closed. The information is gained through federal oversight agencies, the courts, statewide medical licensing boards and professional societies. For the most part, it is a "malpractice system that performs reasonably well in its function of separating claims without merit from those with merit and compensating the latter".[16]

Table 4.

Ratio of Payment Entries Per Active Provider in 2006		
Provider	**Category**	**Amount**
Physicians (includes MD, MBBS, DO, interns/residents)	Mean Payment	$308,838
	Number	12,495
	Median Payment	$175,000
	Total doctors in 2006	774,883
	Payment Ratio for Physicians	1:62
Physician Assistants (PAs)	Mean Payment	$232,066
	Number	113
	Median Payment	$97,500
	Total PAs in 2006	63,609
	Payment Ratio for PAs	1:563
Advanced Practice Nurses (APNs predominantly NPs, but includes CRNA, CNM and CNS)	Mean Payment	$306,310
	Number	264
	Median Payment	$145,000
	Total APNs in 2006	268,293
	Payment Ratio for APns	1:1016

***ANOVA (Scheffe) F=35.58; DF=2;, and p<0.0001; effective sample size n=249,072**

Data for active physicians is from the *Physician Characteristics and Distribution in the U.S.*, 2008 edition, American Medical Association received from Judy Torres, Data Coordinator, Survey & Data Resources, American Medical Association, personal communication, May 14, 2008.

Data for active physician assistants from the American Academy of Physician Assistants Information Update posted at http://www.aapa.org/research/06numberclinpractice06.pdf Retrieved May 13, 2008.

Data for APNs from the National Nursing Survey Report of the U.S. Health Resources and Services Administration posted at http://bhpr.hrsa.gov/healthworkforce/nursing.htm. Retrieved July 12, 2008. NNSR data includes both active and non-active APNs.

Overall Incidence

Significant differences in liability reports exist between doctors, PAs and APNs. Doctors had the highest number of malpractice reports, followed by APNs and PAs. Adverse actions were similar across the three provider groups with doctors leading, followed by PAs and APNs. While liability report incidence is partially explained by differences in number of providers in each group, the ratio of liability reports and the size of the payments make PAs and APNs distinctly less visible in liability exposure when compared to doctors.

Gender

Female patients comprised 56 percent of the total reports in this analysis. For PAs, 48 percent of female patients were involved in malpractice payment reports and for APNs, 59 percent of female patients were involved in malpractice payment reports. These findings may mean that women are slightly more likely to litigate than men against their health care provider. However, it may also account for the fact that women are more likely to see a health care provider than men and, therefore, have a greater number of health care visits.[9] As the greatest difference between gender payments occurred with APNs, who are predominantly women, it is also possible that women have a higher expectation or are more likely to litigate against women. Clinically active PAs are predominately female (having surpassed males in 2000) but were not the predominant gender in PA reports.[1,2]

Reason for Payments

Among reasons for payments in a liability case, four-fifths (79 percent) of physician malpractice payments were for diagnosis, surgery and treatment. For PAs, four-fifths (80.1 percent) were for diagnosis and treatment. For APNs, three-quarters (75.7 percent) of the payments were for anesthesia, obstetrics and diagnosis. Anesthesia and obstetrics were high-ranking reasons (first and second) for payments among APNs, which may be due to the higher proportion of APNs than PAs employed in these areas. If these two reasons were excluded, the ranking of the top four PA and APN reasons for payment would be the same: diagnosis, treatment, medication and surgery. Anesthesia and obstetrics ranked seventh and eighth for PAs and is consistent with PA census reports; few PAs work in anesthesia and obstetrics compared to APNs. According to the 2007 AAPA census, only 0.3 percent of PAs were employed in anesthesia and 2.4 percent in obstetrics and gynecology.[1]

Medication-Related Payments by Reason for Payment

The most common type of medication errors was the same for all three providers: 1) improper management of

Table 5.

Ratio of Malpractice Payments per Provider Type 1991-2007				
Type of Provider	Number of Malpractice Payments	Average Number of Providers	Ratio of Payments to Providers	Percent Probability
Total	249,097	875,241	-	41.6%
PA	1,222	39,751	1:32.5	3.08%
APN*	2,608	171,562	1:65.8	1.52%
Physician	245,267	663,928	1:2.7	37%

medication regimen, and 2) improper technique. Other common errors were consent issues, failure to order appropriate medication, wrong medication ordered and wrong dosage of the correct medication. Errors in administration of medication were ranked third for PAs and APNs and eighth for physicians. One interpretation is that PAs and APNs administer medication orders more frequently than physicians since, historically, doctors tend to delegate the administration of medications to nurses.

Malpractice and Adverse Action Incidence by Year

The reports of malpractice and adverse actions by year for all three providers (albeit small numbers of PA and APN reports compared to physicians), in terms of both percent and absolute number changes, demonstrate an upward trend during the period of study. However an apogee in this trend may have been reached. When malpractice is separated from adverse events, the physician malpractice reports remained flat (<1 percent change in number of reports per year) between 1991 and 2005 and then decreased from 2003 to 2007. A literature search for policy explanations or social phenomena did not reveal why this shift occurred.

The number of PA malpractice reports saw a continual increase, peaking at 135, until 2004 when a jump occurred from 81 in 2001 to 123 in 2002. PA reports have decreased from 2004 to 2007. However, the overall slope of PA malpractice incidence reports from 1991 to 2007 indicated an average change of 12.1 percent per year, indicating an upward trend.

The number of APN malpractice reports was fairly consistent from 1991 to 2000 hovering between 90 and 140, but then saw a large increase from 111 in 2000 to 183 in 2001, with more increases in 2004, 2005 and 2006 (from 168 in 2003 to 264 in 2006). The overall slope of APN malpractice incidence reports from 1991 to 2007 indicated a 7.4 percent average increase per year, producing an upward trend similar to PAs. The slopes for PA and APN malpractice incidence should not be over-interpreted, as the actual number of reports was comparatively small to that of physicians. The largest change in malpractice reports for these three provider types was a 10 percent decline, including a 10.8 percent physician report decline, in 2006.

This analysis documents that litigation and malpractice payments for PAs and APNs from 1991 to 2007 have been rising overall, especially since 2000. In contrast, the number of physician malpractice reports has been steady overall and on a downward slope since 2003. The overall slope providing the rate of change in malpractice incidence for the three provider types combined is flat but skewed by the comparatively large number of physician reports.

Seeking Interpretations for the Results

Explanations for the increase in total number of PA and APN malpractice payment is: there has been a substantial increase in the number of PA and APN providers entering the workforce during the period observed. The workforce of PAs and NPs more than doubled from 1991 to 2007.[1,2] The number of active PAs went from 20,628 in 1991 to 68,124 in 2007, a 230 percent increase.[1,2] Extrapolation from nursing survey reports conducted by the U.S. Health Resources and Services Administration (HRSA) in 1992 and 2004 suggest that the number of APNs in the workforce rose by approximately 143 percent between 1991 and 2004, from 118,761 to 288,960.[6,7] Combined, the increase in PA and APN practitioners from 1991-2007 was 156 percent. The overall increase in malpractice payments for PAs and APNs from 1991 to 2006 was 176 percent (123 in 1991 to 340 in 2007). This figure approximates the 156 percent percent increase in the PA and APN workforce. According to data from the BLS, the number of physicians increased by only 14.8 percent between 1991 and 2006.[8] The small increase in doctor NPDB report rates may explain why the incidence of malpractice reports for physicians has remained compar-

Table 6.

Malpractice Claims by Patients' Age and Gender, 2004 through 2007				
	Physician	**PA**	**APN**	**Total**
Fetus				
Male	609	1	25	635
Female	438	1	25	464
Under 1 Year				
Male	1,868	2	92	1,962
Female	1,264	5	71	1,340
1-9 Years				
Male	745	4	25	774
Female	619	12	15	646
10-19 Years				
Male	1,062	14	18	1,094
Female	993	14	26	1,033
20-29 Years				
Male	1,294	16	21	1,331
Female	2,829	23	71	2,923
30-39 Years				
Male	2,616	29	24	2,669
Female	5,180	32	105	5,317
40-49 Years				
Male	3,831	55	46	3,932
Female	5,365	49	67	5,481
50-59 Years				
Male	3,985	45	48	4,078
Female	4,357	28	69	4,454
60-69 Years				
Male	2,834	36	37	2,907
Female	2,842	15	41	2,898
70-79 Years				
Male	1,688	18	23	1,729
Female	1,865	11	28	1,904
80 and Over				
Male	442	3	10	455
Female	731	13	18	762
TOTAL	47,457	426	907	48,788
Total Male	20,974	223	369	21,566
Total Female	26,483	203	536	27,222

atively steady. Second, since the slopes for PA and APN malpractice incidence were increasing compared to physicians, this could be attributed to the fact that PAs and APNs are being held more independently accountable for their provision of medical care. As each profession matures, they see more patients (accounting for 11 percent of all outpatient visits in 2005).[9] Furthermore, the courts tend to treat PAs and APNs as directly liable and separate from their supervising physicians are considered the norm. The inclination is to hold each individual accountable to the community standards and not hold the supervising doctor responsible. Some states have adopted regulations requiring peer review of malpractice claims against PAs and NPs.

PA malpractice payments have decreased since 2004 and may be consistent with the downward slope of all reports during this same period; yet are considered more closely tied to their supervising physicians than APNs. Whether a PA's supervising physician is liable for the actions of their PA has not been reported in any systematic fashion, although they may share the same malpractice insurance policy. Medical practice regulations and state laws inextricably link both PAs and physicians, whereas APNs are governed by nursing boards which legal relationship with, and liability of, a collaborating physician are not as clear and vary by state.

Ratio of Payments by Provider Type

The ratio of malpractice payments per total number of active providers in 2006 for each provider type was 12,495 payments for 774,883 physicians, 113 payments for 63,609 PAs, and 264 payments for 268,293 APNs. Overall the ratios were 1:62, 1:563 and 1:1,016, respectively. The number of malpractice payments does not necessarily equate with the number of providers with payments because, in a few instances, some providers had more than one malpractice payment in 2006 and more than one provider may have been identified with a single payment. Controlling for multiple payments by a single provider was not possible with the aggregated data. Nevertheless, the data indicate that PAs in 2006 were 9.1 times *less likely* to make malpractice payments than physicians, and APNs were 16.4 times *less likely*.

Examining the average number of providers and malpractice reports during the 17-year study period, the ratios of payment reports per provider was 1:2.7 for physicians, 1:32.5 for PAs, and 1:65.8 for APNs. During the same 17-year period, PAs were 12.0 times *less likely* to make malpractice payments than physicians, and APNs were 24.4 times *less likely*.

LIMITATIONS

All studies of this magnitude have limitations and this study is no exception. First, granularity has been sacrificed for anonymity in how the data is reported, analyzed and presented. Second, malpractice claims and adverse actions that are settled out of court generally do not reach the NPDB. Estimates of this percentage vary by jurisdiction

and incident but may be as high as 10 percent. Third, the number of PAs and APNs grew substantially during the last two decades, thus the denominator grew faster than the numerator. Fourth, because there is not a national database for APNs, and the tendency for different APN professional groups to count clinically-active heads differently (aggregating some NPs, CNSs and CNMs as NPs), we were left with using the best source at the time which produced an aggregate number of APNs that included inactive APN providers. The NP role in this analysis had to be part of the aggregate for APNs. Clearly, a national registry of all providers in clinical practice would help refine the numbers presented here. Finally, we are left without understanding the judgment rendered in each case. For example, did the claim have merit and did it meet a standard of negligence, or was it a successful but a frivolous litigation?

The issue of differences in litigation and malpractice payments by specialty is not possible in this study due to the confidential nature of the data. It is not currently possible to control for specialty with data from the NPDB. Comparing the incidence among providers working in the same medical specialty would improve comparison studies of malpractice incidence and payments between provider types.

These findings support perceptions that PAs and NPs pose a low risk of malpractice liability to the public in general and to employers in particular. One reason postulated for this observed low risk is the communication skills that NPs and PAs may provide in patient encounters.[4] Whether PA/NPs have communication skills that reduce liability remains to be researched. Another explanation is that PAs in particular may be risk-adverse and avoid procedures that have high liability profiles such as births and anesthesia.

Important work is needed to further understand the rate of litigation and malpractice by number of visits and types of visits that are managed by physicians, PAs, APNs and other types of providers. The strength of the NPDB is that these violations affect all providers equally under federal law. This analysis of the existing data should offer some reassurance that the delegated responsibility of patient care from the physician to the PA and NP is a relatively safe one. Insurance premiums have not been reported as high as doctors in comparable settings.

The data indicated that, in 2006, PAs had a probability of making a malpractice payment that was 9.1 times *less* than physicians; APNs had a probability that was 16.4 times *less*. For the full 17-year study period, those probabilities were 12.0 and 24.4 times *less*, respectively. Please note that the APN demographic data included both active and inactive practitioners. Therefore the ratio of payments to APN may be misleadingly low. Also, physicians may assume inherently higher malpractice risk than PAs or APNs because of differences in role and autonomy. We may not conclude that PAs and APNs are safer providers of care than physicians with this analysis, only that they appear to have a lower probability of being rendered malpractice payments.

CONCLUSION

The intent of this study was to assess whether PAs and APNs negate any of their cost effectiveness by increasing liability. Seventeen years of observation suggests that, if anything, they may decrease liability, at least as viewed through the lens of a national reporting system. During the first 17-year study period, there was one payment report for every 2.7 active physicians, one for every 32.5 active PAs and one for every 65.8 active and inactive APNs. In percentage terms, 37 percent of physicians, 3.1 percent of PAs and at least 1.5 percent of APNs would have made a malpractice payment during the study period. The physician mean payment was 1.7 times higher than PAs and 0.9 times that of APNs, suggesting that PA employment may be a cost savings for the health care industry along with the safety of patients. When liability occurs, the reasons for disciplinary action against PAs and APNs is largely the same as doctors. Trend analysis suggests that average malpractice payments and total payments may be on a downward trend, with PA and APN trends declining more than doctors. Finally, authority for medical task delegation is based on the legal doctrine of *respondent superior*, which holds that the physician is ultimately accountable for the actions of his or her employees as a supervisor. From a policy standpoint, it appears that the incorporation of PAs and APNs into society has been a beneficial undertaking and liability has not increased, at least compared to doctors. Understanding the finer issues regarding each case will help test the hypothesis that PAs and APNs are in America's best interest.

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IMPLEMENTING A CRIMINAL BACKGROUND CHECK PROCESS

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ABSTRACT

Motivated by external factors and an interest in providing the highest quality of patient care, the University of Iowa implemented a criminal background check process for all health science students in 2004. The authors detail the principles that guided policies and procedures that were put into place at university and collegiate levels to ensure that applicants and students understand the process; that an individualized review of criminal conduct reported in a background check occurs; and that fair and consistent action is taken in cases considered. The number and type of infractions reviewed by the Carver College of Medicine during a four-year period are conveyed as well as national statistics resulting from the criminal background check pilot operated by the American Medical College Application Service. The authors conclude that criminal background checks are an effective tool to be used for screening purposes before students are allowed patient contact but there must be clear procedures that are communicated to applicants and students as well as considered action taken when problematic behavior is uncovered by the check.

In 2004, the University of Iowa implemented a program of mandatory criminal background checks for all health science students. The rationale for this was assuring the highest quality of patient care, and promoting the highest level of integrity in the health professions by determining whether students had any history of violent, threatening or other conduct that could put patients at risk. There were three motivating factors in 2004; first, the requirement by the Joint Commission that staff members undergo criminal background checks was being applied to students;[1] second, some states were implementing statutes or policies requiring background checks of University of Iowa students doing extramural rotations;[2] and, third, there were well-publicized incidents of criminal behavior by health science students that might have been prevented by a background check.[3]

The University of Iowa implemented a two-part system, consisting of self-disclosure by applicants and a criminal background check conducted by an outside entity prior to students enrolling in courses with a clinical practicum component. The background check examined public records in state and federal databases for past incidents and arrests for criminal conduct. "Criminal conduct" was defined as any non-traffic offense or arrest, any felony, any misdemeanor (serious or aggravated) regardless of whether the record has been expunged or the sentence deferred.

A "clinical practicum experience" was defined as a clinical practicum, clerkship, clinical rotation or other educational experience in which the student provides direct patient care, is supervised by a faculty or staff member, but is not always under direct observation. The requirement does not apply to students who have brief job-shadowing experiences, during which they do not provide direct patient care and are under the direct supervision of a staff member.

Prior to conducting the background check, the University obtains the student's written permission, provides required disclosures and obtains the information necessary to conduct the check (date of birth, social security number and previous addresses for seven years). An example of a "required disclosure" is the requirement that each student must receive a document summarizing rights under the Fair Credit Reporting Act, even though no review of student financial history is done.[4]

The University defined several principles for managing the background check process:

1. The two critical issues that must be considered at all times are patient safety and fairness to students.
2. All information derived from a criminal background check is confidential and is shared only on a strict "need to know" basis (defined by college procedures).
3. Colleges need to have procedures that are consistent with University policies, existing collegiate policies and principles of fairness and due process.
4. Procedures must be consistent with federal laws regarding student aid, the Americans with Disabilities Act and other acts to prevent discrimination.[5]
5. Consideration should be given to recognized issues relating to the administration of justice for persons from minority and financially disadvantaged groups.
6. There must be a rationale for and clear documentation of any decision that affects the academic progress or opportunity of a student.
7. Every case will be reviewed individually; there will be a presumption that decisions affecting academic progress or admission will be made only in rare cases.

In analyzing reports of misconduct the guiding principle is that there needs to be a relationship between the conduct and patient care. The conduct needs to be evaluated with regard to whether it suggests that the student poses a risk to patients. This requires, in most cases, collecting additional information about reported incidents and reviewing them in detail with the student to determine if there is a pattern of behavior. Often, this means assessing the student's judgment and maturity level and making a prediction about future behavior.

The University of Iowa initially worked with the following framework for analysis:

1. Minor incident (such as Possession of Alcohol Under Legal Age) (PAULA): up to 3 during the period of review, involving no violent or other illegal conduct and no suggestion of substance abuse: No action/no restriction of access to patients.
2. PAULA plus additional charge (resisting arrest, for example), repeated PAULA charges within short time frame or misdemeanor drug possession: Action: request additional information from student, and review with collegiate committee.
3. OMVUI (Operating a Motor Vehicle Under the Influence of Intoxicants), any act involving intent to harm, presence on abuse registry, presence on sex offender registry, non-violent felony: Action: request additional information from student, collegiate review, conditional admission.
4. Misrepresentation on admission materials about past: Action: denial of admission.
5. Incidents of violent crime, pattern of increasing seriousness of offenses, multiple citations in any area (including domestic violence): Action: these suggest a basis for concern about safety, request additional information, collegiate review, consider denying access to direct patient care.

One issue of concern is the confidentiality of abuse registries. Public record searches will not disclose past reports of child, dependent adult or domestic abuse in the absence of criminal charge. The records of a criminal charge become public records. Reports of abuse, even if they are determined to be legitimate, are not made public or accessible except by statute. There needs to be statutory authority for educational institutions to gain access to abuse registries. Iowa passed a statute in 2006 allowing the Iowa Department of Human Services to disclose the presence of nursing students on its registries, but the resulting data is only applicable to students from Iowa.[6] It does not apply to students in other health science disciplines.

The costs of conducting the criminal background check were passed on to students in the form of a "miscellaneous fee" that was billed when the data was entered to conduct the check. The charge was initially set at $50 (a one-time charge) but after a year of experience, this fee was raised to $100. Costs for the checks vary widely, depending on the number of states that the student has lived in. Some states charge a fee to access public records of criminal convictions, leading to charges that ranged from $12 to $250 in one entering class.

Each Health Science College was required to develop a system for evaluating student responses to the self-disclosure requirement as well as define the range of actions possible when a student either discloses or is found to have a history of criminal conduct.

Much of the information outlined above for the University of Iowa also holds true for the development of the criminal background check process in the University of Iowa Roy J. and Lucille A. Carver College of Medicine (CCOM). Criminal background checks were conducted for all entering medical students as early as 2004 in a response to a request by university hospitals and clinics where medical students complete the majority of their clinical training. The CCOM has a long history of requesting information

about misdemeanors and felonies, charges and convictions, on the Iowa secondary application; however, there was no follow-up to ensure that information was accurate and inclusive until 2004. Like the rest of the university, the CCOM was primarily interested in minimizing risks to patient safety and determining whether concerns would arise with future licensing applications. In the first year of conducting background checks, the CCOM used an external vendor; charged students $100; and turned up three "hits" that needed additional follow up. Of the three, one student was dismissed from the college; one student was required to meet with a dean throughout the first year of medical school; and the last issue was resolved with a single meeting between the student and a dean. From 2005 to 2008, a total of 35 hits were reported as a result of a background check and all were resolved without dismissal or rescinding of an admission offer. Most of the offenses were alcohol-related and all but two were reported on either the American Medical College Application Service (AMCAS) application or on the Iowa secondary application. The two unreported offenses occurred after application materials were filed and the students involved were forthcoming with information when contacted.

The CCOM will only accept applicants who meet both admission and technical standards. As part of the application process, all applicants must sign a background check release form that allows a vendor to complete a full criminal background check on those admitted to the college. If violations greater than minor traffic violations appear in the results of the background check, a copy of the report will be given to the admitted student and he or she will be allowed to respond to the information contained in the report. The secondary application for the CCOM also includes space for applicants who have responded affirmatively to a record that includes a misdemeanor and/or felony conviction to provide additional information.

Information provided in the criminal background check report is confidentially maintained in a secure place and, unless action is taken by the college as a result of the report provided, outside of the student's permanent academic file.

The Admissions Committee reviews all affirmative responses and considers timing, number and the severity of offenses listed. Of equal importance to the committee's review is the applicant's statement about the offense and lessons learned. The decision to admit or deny the applicant will be based, in part, on information provided by the applicant about their criminal record. An applicant denied admission is offered an opportunity to solicit feedback from the committee and information about how their criminal record contributed to the final decision will be relayed.

Admitted students who have criminal records reported on the background check and not reported on their application through the AMCAS or on the CCOM secondary application undergo another review by the Admissions Committee when results of the background check are received. The student is allowed to present additional information for the committee's consideration. Again, the timing, severity and number of offenses are considered. The full Admissions Committee votes on any recommended action and a quorum is necessary. The committee may decide to rescind an admission offer as a result of the student's dishonesty. The student has the right to appeal the decision through the normal appeal process.

The process followed at the CCOM is provided in detail to underscore the point that significant emphasis is placed on providing timely information to applicants and admitted students about the criminal background check and on a fair review of check results. Challenges in implementing and maintaining the policies and procedures for the criminal background check process at the CCOM include:

1. Ensuring consistency in actions taken by the Admissions Committee based on a consistent, fair and individualized review of the record
2. Determining relevance of and action to be taken with expunged and juvenile records
3. Whether and how to include information received in a student's academic file
4. How best to integrate policies and procedures with the rest of the health science programs and the national application service
5. Education of applicants, admitted students and the Admissions Committee about the relevance of the criminal background check and potential for action to be taken given a hit

Since the start of a pilot program in 2007, the Association of American Medical Colleges (AAMC) has provided a criminal background check service to both applicants and member medical schools through AMCAS. The CCOM is a participant in the expanded pilot and now directs applicants to AMCAS for completion of the background check. This is a significant time and cost-saving measure for all parties involved. There is no fee for the service and

AMCAS contracts with an outside vendor to process the checks and provide information to the participating medical schools. Students need only complete one release of information and results will be sent to all the participating schools to which they've applied. Information about the number of participants and number and kind of hits provided by AMCAS is included in the table below.

Lessons to be passed on:

1. It is essential that there be clear policies and guidelines so that students know what to expect.
2. Detailed case-by-case review is necessary in almost all instances of repeated criminal conduct, even for minor infractions.
3. Staff members involved in the reviews should be experienced in student services and educated in all aspects of the criminal background check process and its impact.
4. Two states, Minnesota and Oklahoma, require that the student be given the option of receiving a copy of the results of the background check.[7,8]
5. Regular review of policies, procedures and outcomes is necessary to ensure fair and equitable treatment.
6. Students will be subject to criminal background checks several times during their medical education and career: upon admission, upon residency selection, by licensure boards and when applying for privileges at hospitals. Students should be informed of the consequences of violating the law on their education, licensure and future practice.

CONCLUSION

It increasingly has grown critical the university be able to assure that students do not pose any risk to the patients they are caring for. Criminal background checks are an important tool in screening the students prior to patient contact. In implementing a program of criminal background checks, attention must be paid to both procedure and substance. The procedures for the program must be complete, clear and communicated to the students. If the background check uncovers problematic conduct, there must be a clear relationship between the conduct and any action taken that affects the student's ability to matriculate or continue in the academic program. The people involved in decision-making must be educated in the relevant areas of the law, due process and student services. Finally, an effective program requires a team effort; admissions officers, faculty and administration must work together with the goal of patient safety and academic integrity, and communication and joint problem solving are keys to success.

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	Entering Class of 2008	Entering Class of 2009**
Participating medical schools*	10	41
Total number of applications processed by AMCAS	40,841	40,475
Applicants applying to at least one CBC-participating school	24,985 (61%)	35,300 (87%)
Applicants who responded "yes" to AMCAS felony, misdemeanor or military discharge question	Felony: 34 (.08%) Misdemeanor: 877 (2.2%) Military dis charge: 10 (.02%)	Felony: 19 (.05%) Misdemeanor: 916 (2.3%) Military discharge: 13 (.03%)
Checks conducted by vendor chosen by AMCAS	2,772	5,343
Hits identified by vendor	Felony: 1 (.04%) Misdemeanor: 49 (1.8%) Military discharge: 19 (.69%)	Felony: 3 (.06%) Misdemeanor: 196 (3.7%) Military discharge: 34 (.64%)

***An additional 33 schools have expressed interest for 2010**

****At the time of this writing AMCAS 2009 was not yet closed, so associated data was not final.**

Human Resources Standard 1.20 (2008).
2. See, *e.g* .Medical Student Matriculant Criminal History Records Check Act, 110 ILCS 57 (2005).
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DEVELOPING TEST CONTENT FOR THE UNITED STATES MEDICAL LICENSING EXAMINATION

David B. Swanson, Ph.D., Katherine Z. Holtzman, David A. Johnson, M.A.

ABSTRACT

Developing test content for the USMLE involves significant efforts from physician volunteers and staff associated with the program. The bedrock of this process takes place among the test materials development committees (TMDCs) where physicians and content experts write multiple-choice questions for all three USMLE Steps. Ongoing assessment of the item pool by the respective Step Committees initiates item-writing assignments that bolster or maintain content in specific areas. Staff at the National Board of Medical Examiners (NBME) then assist item-writers to assure a consistent style and structure for all USMLE test items. All test materials are crafted to complement an overall examination blueprint. Multiple levels of review and pre-testing ensure that all test items making their way onto examination forms as live or 'scored' material are appropriate, statistically sound and presented in test forms balanced to be consistent with the content outline and examination blueprint.

INTRODUCTION

Since its implementation in 1992, the United States Medical Licensing Examination® (USMLE) has provided state medical boards with a high quality, standardized national tool for assessing physician knowledge prior to issuing an initial license for unsupervised medical practice. Today, all allopathic and composite medical boards require successful completion of the USMLE as a condition for licensing their M.D. degreed physician candidates.[1]

This article continues the periodic series on the USMLE begun in 2005. Prior articles in the series focused on a broad introductory overview of the program, the Step 2 Clinical Skills (CS) examination and the program's processes for maintaining examination security.[2,3,4] The intent of this article is to provide readers with an understanding of the committee structure and processes for developing USMLE examination content with a particular focus on the development of multiple-choice questions for the exam.

COMMITTEE STRUCTURE

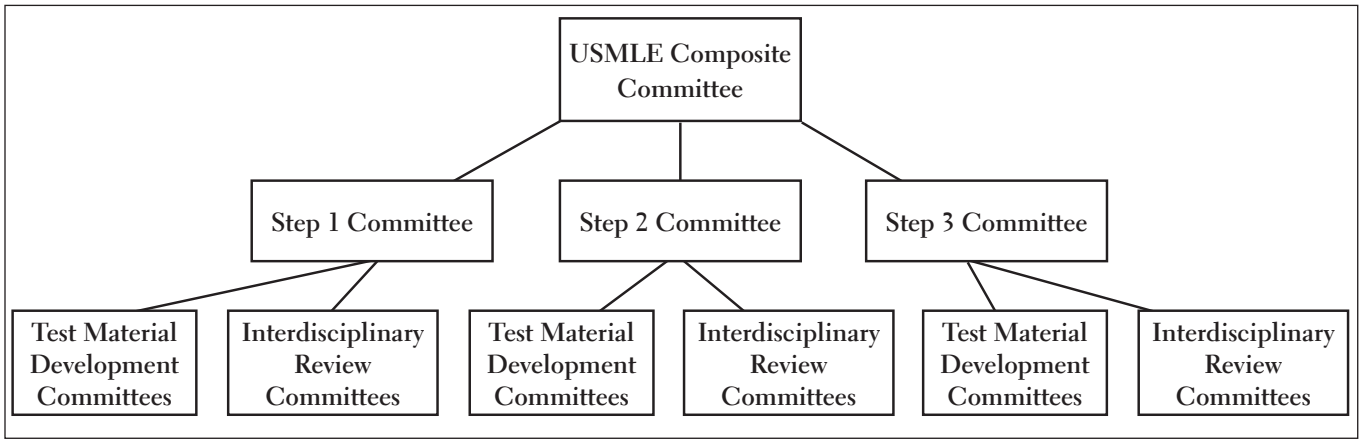
While the USMLE is a joint program of the Federation of State Medical Boards (FSMB) and the National Board of Medical Examiners (NBME), the development of examination content is really a collaborative effort involving the talents and efforts of many individuals working beyond the walls of these two organizations. Much of the work in writing and reviewing test materials is performed by physicians and clinicians drawn from across the country and representing multiple perspectives: the medical licensing community, academic medicine and clinical practice. In this sense, the USMLE relies upon a "national faculty" of experts numbering more than 300 strong and serving on approximately 40 committees.[5,6]

Program governance is conducted through the USMLE Composite Committee, whose appointed members represent the FSMB, the NBME, the Educational Commission for Foreign Medical Graduates (ECFMG) and the American public. The Composite Committee is charged with broad responsibilities for the program, e.g., approval of the exam blueprint for each Step, establishing program policy as well as scoring and standard setting systems.

An examination committee has been established for each of the three USMLE Steps. They are the Step 1, Step 2 and Step 3 Committees. These committees operate under the auspices of the Composite Committee and are charged with designing their respective Step's design, determining testing methods, supervising test item development, approving test forms and setting the pass/fail standard. Appendix 1 offers a description of the USMLE process for standard setting.

Two additional levels of committee work are critical to the development of USMLE test content. Supporting each Step committee are several Interdisciplinary Review Committees (IRCs) and multiple Test Materials Development Committees (TMDCs) (see Figure 1). The latter serves as the foundational base for USMLE test development as it is the members of these committees who write the test

Figure 1. USMLE Committee Structure



items that ultimately appear on the USMLE. The majority of the USMLE program's national faculty work as item writers on TMDCs.[7] The efforts required by the TMDC members to produce high quality test items far exceed the modest rewards offered in return: a small honorarium and limited number of continuing medical education hours. The IRCs provide a review and quality control function for materials developed by the TMDCs. This is covered more fully in the section "The IRC: Review and Approval of Live Materials."

Newly appointed TMDC members attend a multi-day item-writing workshop in Philadelphia conducted by NBME staff to orient the new members to the mechanics and style of writing test questions for the USMLE. Afterward TMDC members receive assignments to write questions in their area of expertise. When a TMDC committee re-convenes in Philadelphia, they will collectively review and critique drafted items and review performance data for items that have been pre-tested previously with examinees. See Figure 2 for an overview of the test development process.

In speaking with current and former members of TMDCs, a common theme often arises from the conversation. For the committee member, the true rewards of participation stem from the collegial nature of the test development enterprise, the opportunity to meet and interact with fellow physicians from across the country and a satisfaction that they are "giving back" to the medical profession they love.

Developing multiple choice questions (MCQs) for USMLE

While the USMLE provides insight into clinical and communication skills through Step 2 CS and patient management through the Primum® computer case simulations on Step 3, MCQs comprise the majority of the content for assessing physician knowledge in the USMLE sequence. In 1999, the USMLE program moved to a computer-based form of test administration with testing offered year-round. The latter element requires a test pool of many thousands of items for each Step. This allows the USMLE program to create multiple test forms for each Step while minimizing any duplication in content that examinees will see. Maintaining a test pool of high quality MCQs for each Step is a critical activity of the program.

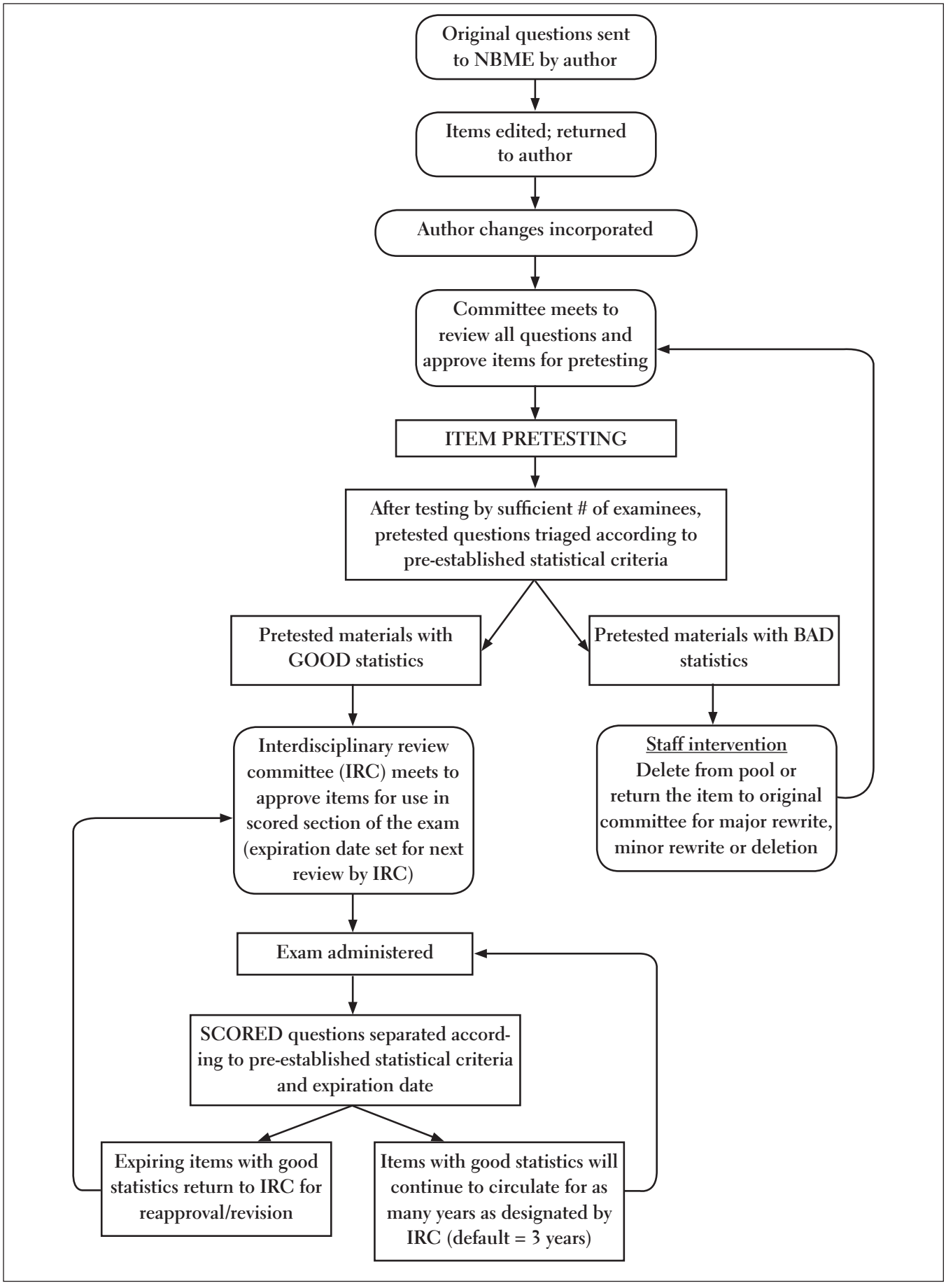
Pool Analysis and Assignment of Items

Before items are assigned or written for a USMLE Step, an analysis of the item pool is conducted to identify topic areas in the pool that are shallow or deep. The purpose of this exercise is to identify areas of the item pool that need particular focus in a given year to build up test content. TMDC members are asked to write new items in shallow areas to level the test pool and increase the number of non-overlapping test forms that can be constructed.

Preparation and Submission of New Items

TMDC members are typically asked to write approximately 50 new items annually. This allows USMLE to address shallow areas or replace content scheduled for retirement. The work of the TMDC members is done at their home or home institution. Items, including any associated pictorial materials, are submitted to NBME editorial staff. The USMLE encourages item writers to include pictorial materials with a large percentage of their items. These pictorial materials may include graphs or drawings, clinical photo-

Figure 2. Typical Item Development Cycle



graphs depicting physical findings, gross or histopathological specimens or results of commonly encountered diagnostic studies (e.g., ECGs, x-rays, MR scans). In 2007, the USMLE program began including a small number of test items in Step 2 Clinical Knowledge (CK) that use audio and/or video clips of physical findings and doctor-patient interactions. Similar multimedia items were phased into Step 1 and Step 3 in 2008.

Interim Editing

Upon receiving items from TMDC members, NBME test development staff place the items into a tracking table and verify that all key components required for each item have been included (i.e., answer key, content classifications, associated pictorials); authors are contacted to supply any missing information. Figure 3.1 illustrates how an item might read at this early stage of development. Most items are in the form of a patient vignette in which the first sentence provides the patient age, gender, site of care, presenting complaint and its duration. Subsequent sentences in the vignette provide additional patient history, physical findings, the results of diagnostic studies and/or response to initial treatment. A staff editor reviews the item to see that it conforms to the requested USMLE style and to ensure no information is missing. Staff also edit and annotate items for clarity, grammar and punctuation, uniformity of style and technical item flaws – particularly those that might otherwise benefit test-wise examinees or add irrelevant difficulty. Edited items (Figure 3.2), along with the original versions, are returned to item writers for revision and approval before being incorporated into a draft for review at the TMDC meeting.

Review and Approval of Item Revisions by Item Authors

Authors review their edited items, respond to queries from the staff editor, verify the correct answer and classification codes, and confirm the appearance of any associated pictorials. Any disagreements about phrasing are generally negotiated between the editor and author in order to arrive at a consensus about the version to be included in the draft of materials for review at the TMDC meeting. On the rare occasions when consensus cannot be reached, both the author's and editor's version are included in the draft.

Review and Approval for Pre-testing at the TMDC Meetings

A draft of test materials that includes the final approved version of each item is mailed to all TMDC members prior to their scheduling meeting. During the three-day meeting, all items are read aloud by the author, and a decision is made by the TMDC to accept, rewrite or delete each item. A staff editor facilitates discussion, assists in refining items and maintains an official record of all committee decisions, including text and classification changes and final disposition of the item. The committee chair assigns a quality grade for each item. These grades are used when selecting items for placement in examination forms. The overall acceptance for items reviewed at TMDC meetings is typically at or above 90 percent.

Pretesting

Following the TMDC meeting, all accepted items are updated to reflect the final phrasing approved at the meeting. The revised items receive one more review by the editor to ensure accuracy and adherence to style. An assigned staff proofreader then reviews all items for grammar, punctuation and uniformity of style. (Figure 3.3) Any questions that arise about content during this phase are discussed with the relevant TMDC chair and revised as needed.

Finalized items are uploaded into the NBME item bank and made available for pre-testing. Pretest items are included in live test forms administered to examinees; however, as pretest material they are unscored and, thus, not used in determining the examinee's pass/fail outcome for that administration. Pretest items are not identified as unscored material to the examinee. In this way, an accurate assessment of the item's performance can be obtained. Each MCQ is pre-tested by a minimum of 200 examinees in order to project the statistical characteristics of the item (e.g., item difficulty, discrimination†).

The IRC: Review and Approval for Live Materials

The purposes of the IRCs are to (1) annually review and approve newly pre-tested items (along with statistical performance) into the live, i.e., scored, pool and (2) re-review and re-approve expiring items currently in the live pool for continued use. Once approved for live use, each item is scheduled for re-review for continuing use three years later. Approximately one-third of the live (i.e., scored) pool is reviewed annually for continued accuracy and relevance.

In order for pre-tested items to be selected for review by an IRC, the item difficulty (i.e., proportion of students answering the question correctly or p-value) and discrimination index must meet prescribed statistical criteria. These vary somewhat by Step. In general, however, MCQs must have an item difficulty or p-value of greater than 30 percent and less than 97 percent. The discrimination index must have a positive correlation (i.e., most examinees from

Figure 3. Sample MCQ Item Showing Editing Process

3.1 Original Question Sent by Author

A six-year-old male is seen in the pediatrics clinic. He has limb shortening, macrocephaly with frontal bossing and mid face hypoplasia, exaggerated lumbar lordosis, genu varum and trident hand. Genetic evaluation reveals a mutation of the code for fibroblast growth factor receptor three. Which of the following is true?

(A) Patient has achondroplasia
(B) Patient has osteogenesis imperfecta
(C) Patient has autosomal recessive disorder
(D) Patient has a sex linked disorder
(E) Most patients with this disorder also have abnormal procollagen synthesis
(F) Growth hormone has no effect on bone growth in this abnormality

3.2 Initial Edit: Returned to Author

A six-year-old boy is brought to the physician by his mother because of concern [about his short stature? He feels well? He has no history of serious illness and takes no medication? Immunizations are up-to-date?]. He is at the __th percentile for height and the __th percentile for weight. Examination shows a large head, a prominent forehead and mid face hypoplasia [a flat nasal bridge?]. There is lumbar lordosis. Examination of the upper and lower extremities shows decreased length, a tridentate appearance of the fingers on extension, and a bowleg deformity. Genetic testing shows a mutation of the code for fibroblast growth factor receptor three. [OK to omit or replace with x-ray findings? Would a pediatrician have genetic testing done for this case?] Which of the following is the most likely diagnosis?

(A) Achondroplasia
(B) Osteogenesis imperfecta
(C) _____? [specify an autosomal recessive disorder?]
(D) _____? [specify a sex linked disorder?]
(E) _____?
(F) _____?

Note: Please rewrite as shown to eliminate the true/false format. Also, would this have been diagnosed earlier in this patient? Can he be younger?

3.3 TMDC Version Incorporating Author's Changes

A six-year-old boy is brought to the physician by his mother because of concern about his short stature. He feels well. He has no history of serious illness and takes no medication. Immunizations are up-to-date. He is at the 7th percentile for height and the 11th percentile for weight. Examination shows a large head, a prominent forehead and a flat nasal bridge. There is lumbar lordosis. Examination of the upper and lower extremities shows decreased length, a tridentate appearance of the fingers on extension, and a bowleg deformity. Which of the following is the most likely diagnosis?

(A) Achondroplasia
(B) Osteogenesis imperfecta
(C) Gonadal dysgenesis 45, X (Turner syndrome)
(D) Leri-Weill syndrome
(E) Noonan syndrome

the top half of performers must answer the question correctly and most examinees from the lower half of performers must miss the question).

A draft of test materials is mailed to all IRC members prior to their scheduled meetings. In preparation for the multi-day meeting, members are assigned to review a specific subset of items; the reviewers are responsible for presenting these items during the meeting. For pre-tested items, reviewers are instructed to consider the appropriateness of each item

3.4 Administered in Exam as Pretest

Item Stem: SCBB5064

A six-year-old boy is brought to the physician by his mother because of concern about his short stature. He feels well. He has no history of serious illness and takes no medication. Immunizations are up-to-date. He is at the 7th percentile for height and the 11th percentile for weight. Examination shows a large head, a prominent forehead and a flat nasal bridge. There is lumbar lordosis. Examination of the upper and lower extremities shows decreased length, a tridentate appearance of the fingers on extension, and a bowleg deformity. Which of the following is the most likely diagnosis?

(A) Achondroplasia
(B) Gonadal dysgenesis 45,X (Turner syndrome)
(C) Leri-Weill syndrome
(D) Noonan syndrome
(E) Osteogenesis imperfecta

Exam Admin	Exam Instance	Use	Bk	Pres	Seq	p	rb	r	Pop	Medley ID
Step 2-0301	STP2C/ST9	P	S	0001	8636	83	+20	+14	283	MBK1802

Subgroup Statistics: STEP 2–0301 STP2C/ST9 MBK 1802

M	*O*	A	B	C	D	E	
0	0	91	0	0	5	4	High
0	0	71	0	9	13	7	Low

3.5 Administered in Exam as Live

Item Stem: SCBB5064

A six-year-old boy is brought to the physician by his mother because of concern about his short stature. He feels well. He has no history of serious illness and takes no medication. Immunizations are up-to-date. He is at the 7th percentile for height and the 11th percentile for weight. Examination shows a large head, a prominent forehead and a flat nasal bridge. There is lumbar lordosis. Examination of the upper and lower extremities shows decreased length, a tridentate appearance of the fingers on extension, and a bowleg deformity. Which of the following is the most likely diagnosis?

(A) Achondroplasia
(B) Gonadal dysgenesis 45,X (Turner syndrome)
(C) Leri-Weill syndrome
(D) Noonan syndrome
(E) Osteogenesis imperfecta

Exam Admin	Exam Instance	Use	Bk	Pres	Seq	p	rb	r	Pop	Medley ID
Step 2-0401	STP2C/ST10	L	S	0001	5665	83	+29	+19	1078	MBK1802

Subgroup Statistics: STEP 2–0301 STP2C/ST9 MBK 1802

M	*O*	A	B	C	D	E	
0	0	92	0	2	5	1	High
0	0	76	1	2	12	9	Low

for the examination purpose (e.g., all items approved for use on the Step 2 CK exam must be appropriate for all new interns regardless of specialty) and to verify all classification codes. Live items are reviewed for currency and continued appropriateness for the examination's purpose.

At the meeting of an IRC, all items are read aloud by the assigned reviewer who makes a recommendation about disposition (See Figure 3.4 and 3.5 for examples). The committee then takes one of the following actions for disposing of each pretest and expiring live item.

- Approved for inclusion in the live, (i.e., scored) pool – The item is accepted as written.
- Return for pre-testing – Minor revisions are required that can be made at the meeting but the item will be sent back to be pre-tested again.
- Send back to TMDC for revision – Content is acceptable but major revision is required.
- Delete from the pool – Content is inappropriate.

A staff editor facilitates discussion and records all committee decisions, including classification changes and final disposition of the item, as well as any notes to be sent back to the TMDCs.

Test Form Approval

Once test items have been approved by the IRC for inclusion in the live pool, these materials are then available for placement in test forms (as scored items) for their respective Step examinations. The Step Committees are responsible for review and approval of their respective test forms. This occurs annually during a multi-day meeting when the Step Committee reviews each test form prior to its utilization in test administration. Prior to this meeting, staff has already created multiple parallel test forms following the exam blueprint previously established and approved by the respective Step Committees.

Year-round testing in a computer-based format requires thousands of test items and multiple forms of each USMLE Step examination. The focus of the Step Committees in reviewing each test form is to ensure appropriate 'balance' in each form (i.e., that no test form is under or over-represented in certain content areas).

SUMMARY

In 2008, the USMLE program administered approximately 140,000 Step or Step component examinations in the United States and around the world. One need only ponder this number to gain some appreciation for the labor and resources necessary to develop and maintain high quality examination content for the USMLE. The physicians and staff members associated with the program consider the USMLE the "gold standard" for medical licensing examinations. Maintaining this high standard remains a priority so that state medical boards may continue to rely upon the USMLE a quality independent assessment tool supplementing their judgment in the decision to grant an initial medical license.

*Non-overlapping refers to test forms whose scored content is not duplicated on another test form.

†Item discrimination reflects the differing performance on a question between individuals whose overall score is among the top half of examinees as opposed to examinees whose overall score is in the lower half. For a test question to be a good discriminator, most of the upper group should get the question right and most in the lower group should miss it.

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APPENDIX 1: STANDARD SETTING

The USMLE program provides a recommended pass or fail outcome on all Step examinations with numeric scores reported for Step 1, Step 2 CK and Step 3 in the form of a two- and three-digit scaled score. The recommended performance standards for the USMLE are based on a specified level of proficiency identified through a standard setting process. As a result, no predetermined percentage of examinees will pass or fail the examination.

Approximately every three years, each Step committee revisits its standard, i.e., minimum pass score. In discussing the appropriateness of the current standard, Step committees consider information drawn from multiple sources:

- recommendations from independent groups of physicians who have participated in content-based standard-setting activities;
- survey results from various groups such as state medical boards, medical school faculty, and examinees;
- trends in aggregate examinee performance data; and
- data on score precision and its effect on the pass/fail decision.

The content-based standard setting activities offer an especially important piece of data. This process involves in-

dependent panels of content experts. Participants on these panels are drawn from the medical licensure and undergraduate and graduate medical education communities and typically have had no prior experience writing test content for the USMLE program.

The panels begin by reviewing previously used test questions and rendering a judgment about the likelihood of a minimally proficient candidate correctly answering these questions. The panels then receive data detailing actual examinee performance on these questions. This provides the opportunity for panelists to reassess their concept of a minimally proficient examinee and revise their estimates for projected performance. Having completed this first phase of the process (i.e., judgment, feedback), the panels are then asked to review a new set of questions and make performance projections for minimally proficient examinees. Using the data derived from this second round of assessment by the panelists, staff then prepares a tentative minimum passing score based upon these experts' judgment for subsequent review and consideration by the respective Step committee.

In addition to the results from these standard setting panels, the Step committee also reviews the results of surveys previously sent to representatives from licensing boards, the medical education community and examinees. The surveys questioned respondents on acceptable and unacceptable failure rates. By adding in data showing trends in examinee performance for that Step as well as psychometric details on score precision, the Step committee is able to address the fundamental question before them: "Do these data suggest a need to change the current minimum pass score?" If the answer to this question is "no", the Step Committee decides to maintain the current standard; if "yes," the committee then decides how much to change the current minimum passing score.

APPENDIX 2: PARTICIPATING WITH USMLE

Maintaining the high quality of its "national faculty" is a priority for the USMLE program. Staff associated with the program maintains a candidate database of prospective potential appointees to USMLE committees. Preserving a strong presence of physicians with state medical board experience is considered critical. Since 2007, the FSMB and NBME have hosted an annual item-writing workshop for state board members designed to provide attendees with a solid understanding of the USMLE program and the program's approach to writing high quality test questions. To date, 33 physicians representing 28 state medical boards have participated in these workshops.

Members of state medical boards with an interest in attending an item-writing workshop for state board members and/or participating in the USMLE program should submit their curriculum vitae to David Johnson, FSMB Vice President for Assessment Services, at P.O. Box 619850, Dallas, Texas 75261-9850 or via email: djohnson@fsmb.org.

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ALBERTA, CANADA
DRAFT STANDARD FOR TERMINATION OF PREGNANCY

Council continues to work through and refine the draft Standards of Practice for Alberta's medical profession. Having reviewed and edited all but two of the standards at its March meeting, Council expects to have completed its work and to have ratified the standards when it meets in June.

The draft standard on termination of pregnancy has generated a great deal of feedback. Most respondents take exception with the draft, believing that the College will require physicians to refer patients for termination of pregnancy, or at the very least to be compliant in arranging a patient's abortion, contrary to the physician's personal beliefs. This is not true. Some also argue that the physician's individual moral conscience should be the inviolable principle to which all other obligations are secondary.

Recognizing the emotion around therapeutic abortion, here is some context around this issue:

- Termination of pregnancy is a legally available medical procedure.
- Under Canadian law, the unborn fetus does not have status of a person. The *Code of Ethics* states physicians should:
    - Consider first the well-being of the patient;
    - Inform patients when a physician's personal values would influence the recommendation or practice of any medical procedure the patient needs or wants; and
    - Provide patients with the information they need to make informed decisions about their medical care, and answer their questions to the best of their ability.

The College's current policy (in place for the past decade) states:

- While recognizing the varied personal convictions of physicians it must still be the responsibility of physicians to ensure that pregnant women who come to them for medical care are provided with or are offered access to information or assistance to enable them to make informed decisions on all available options for their pregnancies including termination.

The important are these:

A Standard of Practice on this subject will not change the obligations of physicians that have been accepted by this College since 1991. The words are a little different, but the intent is not, as the principles underlying the standard have not changed during the past 20 years.

Physicians have the same obligations to provide informed consent (the information that a reasonable person would want to have) to patients who are pregnant as they have to patients with any medical condition. This information might include the natural history of the condition, the options available, and the risks and benefits associated with the various options. The situation is no different for a patient who presents with a new pregnancy, nor when a patient is seeking an abortion. The exception is when the physician's personal values would influence the recommendation or practice of any medical procedure. In that situation, we (and the *Code of Ethics*) offer the physician an option.

The issue here is not the physician's individual moral beliefs or conscience. As a physician, and a medical professional, physicians must first consider the well-being of their patients (*Code of Ethics #1*). They also must, as professionals, resolve conflicts of interest in the best interest of patients (*Code of Ethics #11*).

Understandably, this standard places some physicians in a difficult moral quandary. The option available to those with such moral distress continues to be to refer the patient to another physician or resource that will provide the patient with all available medical options so that the patient can make an informed choice. By doing so, our members will be acting professionally and will affirm their obligation to put their patients' interests above their own.

OFFICE PROCEDURES REQUIRING COLLEGE APPROVAL

Office procedures requiring College approval now will be listed in the CPSA Standards of Practice. Physicians seeking College approval to perform a procedure on that list must now submit evidence of satisfactory educational qualifications, and compliance with any other practice requirements adopted by Council. Physicians' privileges granted by a public health authority in a facility administered by that health authority are not subject to this regulation.

Previously, only those procedures limited to accredited non-hospital surgical or diagnostic facilities were subject to College approval. Currently, acupuncture and hair transplantation are the only office procedures requiring approval from the College. Acupuncture has required College approval since 1991. Approval is granted to physicians who provide evidence of successful completion of a recognized training program including:

- The Acupuncture Foundation of Canada program
- The Acupuncture Certificate Program at the University of Alberta
- The McMaster Medical Acupuncture Program

Hair transplantation recently was added to this list after consultation with providers and Council advisory committees. Approval for hair transplantation will be granted to physicians who demonstrate sufficient education and experience in the procedures and the operation of a hair transplant practice. Those practices must also demonstrate compliance with infection prevention and control requirements, including the cleaning, disinfection and sterilization of medical equipment.

With this recent addition, all physicians who currently perform hair transplants must immediately begin the approval process.

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BRITISH COLUMBIA, CANADA
AGREEMENT ON INTERNAL TRADE

The Agreement on Internal Trade (AIT) was signed in 1994 by federal, provincial and territorial governments with the intent to reduce or remove inter-provincial barriers to the movement of workers, goods, services, and capital. Chapter 7 of the agreement, which was amended and signed on Dec. 5, 2008, outlines the commitment to achieve full labor mobility in regulated trades and professions in Canada. The provisions in the amended chapter were implemented on April 1, 2009.

Currently, through our national credentialing examinations, physicians have the benefit of mobility across Canada if they hold a Licentiate of the Medical Council of Canada (LMCC), and have certification with either the Royal College of Physicians and Surgeons of Canada or the College of Family Physicians of Canada. Physicians with these credentials have met the standard for full licensure in every Canadian jurisdiction, and therefore face no barriers to portability of licensure other than the requirement to apply for licensure. The amended Chapter 7 now grants mutual recognition to physicians who hold licenses in categories other than full, including provisional, temporary, conditional or restricted.

By statute, the College has the authority to regulate the practice of medicine, including establishing standards for licensure. However, under the AIT, the provincial and territorial governments have agreed to reconcile differences in standards for licensure, and to mutually recognize qualifications of workers certified in at least one Canadian jurisdiction. Whether this will result in a national standard for licensure that ensures that only competent and qualified physicians are duly licensed, or a "race to the bottom" that codifies the lowest standards, remains to be seen.

The Federation of Medical Regulatory Authorities of Canada (FMRAC) and its member Colleges have raised concerns with government regarding the amendments to Chapter 7 of the agreement. The concerns include a lack of meaningful consultation with the medical regulatory authorities, and a lack of defined process to deal expeditiously with any adverse consequences arising from the implementation of the AIT. This College is firm in its belief that it is not in the public interest to wait and see if things go sideways. For example, the AIT does not address the fundamental problem with medical care in Canada: an alarming shortage of physicians. Increasing mobility of a limited supply will undoubtedly exacerbate the maldistribution of physicians that currently exists in Canada. Inevitably, access to medical care will be further limited by a mobility agreement that potentially drains scarce resources away from remote areas that are already underserved.

The College Council and staff will continue to work dili-

gently with FMRAC, its members, and the relevant ministries to ensure that patient access and safety concerns are front and centre. On short notice, an in-person meeting has been scheduled in late March with all of the regulatory authorities across Canada to review and discuss the collective challenges and to seek national solutions. The Ministry of Health Services has been informed of this College's concerns, and we will put forward legitimate objectives in the next few weeks. A number of working groups of the Registration Departments across Canada are attempting to synchronize and align registration processes – with a goal of ensuring that only competent and qualified physicians receive a license, and that national standards for revalidation are upheld.

While we embrace the positives of labor mobility, we must ensure that licensure in any one jurisdiction in Canada cannot be viewed as a "flag of convenience." To address this challenge, we must have a high level of regulatory cooperation across Canada, including current, comprehensive databases from which to share timely information.

Several physicians have contacted the College with questions about the AIT, specifically about whether or not the agreement allows them to relocate to another jurisdiction without full licensure. Since health care is still regulated at the provincial level, physicians wishing to practice medicine in a province or territory must hold a license in that jurisdiction. Requirements for Certificates of Professional Conduct are still necessary when a physician moves from one jurisdiction to another.

AN UPDATE ON EHEALTH

Patient privacy issues

The College continues to be actively involved in provincial eHealth initiatives and is currently represented on the following committees: BC eHealth Council, Physician Information Technology Office (PITO) Steering Committee, eDrug Steering Committee. The College has recently been invited to the Provincial Lab Information System (PLIS) Steering Committee. Progress on patient privacy issues has been slow. However, the College met with the Minister of Health Services in December and again in February, and is encouraged by his commitment to address the following outstanding issues in 2009.

Role-based access model

Electronic Medical Records (EMRs) facilitate the sharing of patient information with other health providers and agencies, such as the Health Authorities. What type of information should be shared with whom, and in what circumstances, must be carefully considered. Government recently established the Clinical Integration Advisory Committee (CIAC), which will be providing recommendations to the Minister, the Office of the Information and Privacy Commissioner (OIPC), the British Columbia Medical Association (BCMA) and the College by June 2009. The College is a participant on this important new committee.

Disclosure directives

The BC eHealth Act passed this spring enables creation of Health Information Banks (HIBs), e.g. Health Authority Electronic Health Records (EHRs). The Minister of Health Services has the authority to authorize individuals to make disclosure directives respecting their own personal health information. It is critical that patients maintain the right to mask identifiable information should they choose. The notable exception would be "break the glass" provisions in emergency situations. Disclosure directives are also being reviewed by the CIAC referred to above.

Physician information technology office (PITO)

Approximately 1,000 additional physicians will be approved for PITO electronic medical record (EMR) systems in 2009. The College continues to support the PITO initiative, however, the recent "Communities of Practice" initiative including larger, more disparate groups of physicians causes some concern. The College encourages Community of Practice physicians to look carefully at the degree to which identifiable information is being shared and ensure that patient privacy is not compromised. Physicians are encouraged to contact either the College or the Canadian Medical Protective Association (CMPA) before entering into a new type of information sharing arrangement.

Third party services

The College is receiving increasing numbers of inquiries from physicians with EMRs regarding contracting out/delegating administrative services to third parties, e.g. transcribing, patient scheduling, document scanning. The College reminds physicians of security breach risks when engaging third party service providers. Physicians should ensure compliance with the BC Personal Information Protection Act (PIPA) and College policy. Generally, it is not acceptable to delegate these services to out of country providers without informed, individual patient consent. Physicians should contact either the College or the CMPA

before entering into this type of third party arrangement.

Privacy toolkit
The College is pleased to report that it is working with the BC Medical Association and the Office of the Information and Privacy Commissioner to update the 2004 Physicians' Privacy Toolkit, which was completed in spring 2009.

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ONTARIO, CANADA
ISSUES AROUND OPIOID PRESCRIBING CAN OVERWHELM PHYSICIANS

"We feel doomed to failure before we even start."

That was the comment expressed by one family physician in a recent survey the College undertook to get a sampling of physician attitudes around pain management and opioid prescribing.

"Most new physicians do not want anything to do with dispensing narcotics to chronic pain sufferers," was the comment from another doctor.

In fact, that survey found that of all the issues doctors face in family medicine, family physicians rank chronic pain management second only to mental health as a clinically challenging area.

Why is this issue fraught with so many difficulties? Consider the landscape. The Centre for Addiction and Mental Health cites prescription opioids as the second most common drug abused by teenagers. In Ontario, individuals in methadone clinics are more likely to be addicted to prescription drugs than they are to street drugs like heroin. Now add the lack of physician education about opioids to the mix – a study by the Canadian Pain Society found that veterinary students receive, on average, three times more designated hours of pain education than students in Canada's medical schools.

It's no surprise then, that underprescribing is every bit as much of a problem as over-prescribing. The Canadian Pain Society has referred to the state of under-treated pain in Canada as a "crisis," when one considers the number of Canadians who suffer from chronic pain – the kind of intractable pain that keeps them from sleeping at night, holding down a job, and enjoying their lives.

It's an unfortunate situation given that the evidence shows that, with appropriate prescribing and monitoring, opioids may indeed be an appropriate drug therapy for some chronic pain patients.

The College, for its part, has been vocal in correcting any impression that it is "anti-opioid" and has gone on record stating that narcotic therapy for chronic non-malignant pain has never been on trial. In my first communication with the profession as College Registrar, I stated: "Physicians who have run afoul of professional standards in regard to pain care have done so because they refused to adhere to basic medical principles, not because they have prescribed opioids," says Rocco Gerace, M.D., College Registrar.

Notwithstanding this pronouncement, the reluctance to manage pain persists. We don't want to inhibit physicians from appropriately prescribing opioids to those patients who need drug therapy to alleviate pain. We recognize that the issues around opioid prescribing can be complex and overwhelming for physicians. We don't want physicians to feel as though they have been abandoned to find their own way through this rough terrain.

That is why Council has made a pledge to finding solutions to the concerns that surround opioid prescribing by identifying the issue as a key public policy priority. We hope to make recommendations to the ongoing problems in this area. For example, how can practitioners – whether doctors or pharmacists – be assisted in recognizing drug-seeking behavior? How is the provision of pain management best managed with the input and cooperation of all care providers and patients?

Effective solutions will require partnerships and collaboration with several different stakeholder organizations to develop public policy solutions and advise and influence government. Some of the projects already underway include a research project funded by the Canadian Patient Safety Institute (interdisciplinary education methods for safer opioid prescribing) and a peer education initiative with the Ontario College of Family Physicians.

The project that is most likely to come to fruition in the short-term, however, is a national guideline on opioid use for chronic non-cancer pain. This is a collaborative project of all of the medical regulatory authorities of Canada. The

goal is to develop, implement to practice, and evaluate the impact of guidelines on the safe and effective use of opioids for non-cancer pain – guidelines that are based on the best available evidence and expert opinion consensus.

A draft of the guidelines should be ready for broad consultation shortly, with input from physicians solicited through *Dialogue* and the College's website.

EXCEPTION PROPOSED FOR USE OF SPECIALIST TITLES REGULATION

Council endorsed a proposed exception to the Use of Specialist Titles regulation that attempts to address both the protection of patients and the ability of physicians to accurately describe their practice.

The Use of Specialist Titles regulation is an important part of the College's four-point plan to address problems relating to the provision of cosmetic procedures in Ontario.

The original amendment stated that physicians were only permitted to use terms, titles or designations in their promotional and advertising materials if they were certified and recognized in that specialty.

During the consultation, the College heard from physicians concerned that their area of certification or recognition did not reflect their current area of practice. Examples of this include a general practitioner who provides psychotherapy exclusively or a family medicine specialist who completed extra training in dermatology and now provides dermatological services primarily.

The proposed regulation exception would allow physicians who have focused practices, or who have completed additional training, but are not certified specialists, to describe their practices in their advertising and promotional materials.

Specific criteria for style and format must, however, be met: physicians must include their own specialist or subspecialist information, in keeping with the existing requirements of the regulation; the phrase, "practicing in" must precede any descriptive terms, i.e., "Dr. X, General Practitioner practicing in anesthesia.

There also are restrictions on the use of some terms. 'Surgeon' and 'surgery' can only be used by certified or recognized surgeons; 'plastic' can only be used by certified or recognized plastic surgeons.

MANDATORY CPD AND THE THIRD PATHWAY

Council agreed that physicians who are not members of either national college would be permitted to rely upon a separate monitoring program to track their Continuing Professional Development (CPD).

This option would allow physicians to fulfill their mandatory CPD obligations to the College without reliance upon either the Royal College of Physicians and Surgeons of Canada or the College of Family Physicians of Canada.

No such alternative monitoring system currently exists and the College would need to approve the system before physicians can rely on it. Final acceptance of such a system will be contingent on it meeting certain criteria, including maintenance of the standards as established by the national colleges, an arm's length auditing system and a mechanism to the College by which failure to meet the established educational benchmarks would be reported to the College.

We will continue to ask physicians about their CPD on the annual survey and work will continue on development of the necessary regulations.

ALABAMA
ACT EXPANDS PA PRESCRIBING

At the request of the Alabama Board of Medical Examiners and the Alabama Physician Assistants' Association, Representative Ronald Johnson, a practicing pharmacist who serves in the State House of Representatives, introduced and passed House Bill 484, enacted as Act No. 09-489, which for the first time allows the prescribing of drugs listed in Schedules III, IV and V by a physician assistant (PA). The Act provides for a Qualified Alabama Controlled Substances Certificate (QACSC) to be issued by the Alabama Board of Medical Examiners to qualified PAs with approved registration agreements with Alabama physicians. The bill does not restrict the number of registrations to a physician in which a PA may be actively involved. In addition to a QACSC, PAs who prescribe controlled substances will have to obtain certain registrations from the U.S. Drug Enforcement Administration, and interested persons are encouraged to visit the DEA's website at www.deadiversion.usdoj.gov/drugreg/index.html to review their regulations and procedures.

The new legislation also establishes the qualifications required for a PA to apply for a QACSC and requires that applications be approved by the Alabama Board of Medical Examiners, which is responsible for the licensing and registration of PAs. The qualifications are completion of a course or courses approved by the board in the areas of advanced pharmacology and controlled substances prescribing trends and a minimum of 12 months of active clinical employment with a supervising physician. The new law allows the Alabama Board of Medical Examiners to establish rules concerning the application procedures, fees, fines, punishments and the conduct of any disciplinary hearings held relative to the alleged improper use of a QACSC. The board also will promulgate rules providing for grounds for the denial of an application and grounds for disciplinary action against a QACSC.

Under the Act, a PA registered to an approved Alabama physician may be authorized to prescribe medications in Schedules III, IV and V, and formularies and medical regimens may be approved by the board. It will require much thought on the part of those in existing PA/supervising physician relationships and those in the process of establishing new relationships to make certain that both the physician and the PA are in agreement on prescribing authority. PA prescribing authority will provide for the call-in or written prescription of any of the drugs in the approved formulary.

The board is in the process of formulating its rules under this new law, which becomes effective Oct. 1, 2009. Proposed rules will be posted at the board's website: www.albme.org.

PDMP ZERO BASED REPORTING

The Alabama Department of Public Health's Prescription Drug Monitoring Program (PDMP) has added a feature for dispensing physicians to submit a "zero report" when no controlled substances have been dispensed within a seven day period. PDMP rules require weekly reporting, whether or not any controlled substances have been dispensed. The zero based reporting will assist registered dispensers with complying with the rules. Detailed instructions on how to submit a zero based report are available on the PDMP website listed below. The instructions can be located by clicking on the *Dispenser Packet* link located on the left hand column of the website. If further clarification is needed, licensed dispensers can contact the PDMP technical support desk at (800) 225-6998 (option 8).

This information pertains to physicians who *dispense* controlled substances from their offices. Dispensing refers to ordering for and delivering to a patient a controlled substance for the patient's use. Physicians who dispense controlled substances are required to register with the board and report to the PDMP. Dispensing rules do not apply to writing a prescription, distributing pre-packaged samples and starter packs, or administration in the office. For more information on this topic, please see the board's website concerning dispensing physicians.

The PDMP is not only for physicians to report medications they dispense. Any licensed physician can use the PDMP to look up individual patients and access informa-

tion about controlled substances that have been prescribed or dispensed to the patient, including the prescriber/dispenser, date, medication and quantity dispensed. Instructions on registering to query the PDMP can be found at the PDMP website.

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ARIZONA

MULTIPLE SEQUENTIAL PRESCRIPTIONS FOR SCHEDULE II CONTROLLED SUBSTANCES

At its February 2009 meeting, the Arizona Medical Board unanimously approved a new interpretation of the Arizona Revised Statutes regarding multiple, sequential prescriptions for the same Schedule II Controlled Substance.

This action means the board will allow such prescriptions for up to 90 days. William R. Martin III, M.D., of Phoenix, the board chair, stated that the board should remain consistent with federal law, policies and guidelines.

Robert P. Goldfarb, M.D., F.A.C.S., of Tucson moved to conform the board's interpretation with 21 C.F.R. 1306.12(b), regarding prescription writing and dating. This interpretation aligns the board's guidelines with a practice that is currently permitted by the Arizona State Board of Pharmacy and the federal Drug Enforcement Administration (DEA).

If a physician provides multiple, sequential prescriptions to a patient that cannot be filled until a certain date, and yet are all accurately dated, the board will not consider this "predating" or "post-dating." For further information, contact Lisa Wynn, executive director of the Arizona Medical Board.

A REVIEW OF PRESCRIBING LAWS FOR DOCTORS AND PAs

Both the Arizona Medical Board (board) and the Arizona Regulatory Board of Physician Assistants (ARBoPA) have seen a number of recent, unrelated cases involving prescribing violations and have cited the physicians and PAs involved. In light of that, it may be worthwhile to review the statutes regarding certain areas of prescribing. This information can be found in the Arizona Revised Statutes under "Definitions" in the Medical Practice Act and the Physician Assistant Practice Act.

In order to write prescriptions for patients, a physician assistant must first have the approval of that delegated task from the PA Board. Before prescribing prescription medication, a physician or a PA must first establish a professional relationship with the patient. This is done by conducting a physical examination of the patient and – if it hasn't been done before – taking a complete medical history. A.R.S. § 32-1401 (27)(ss) which applies to physicians states that unprofessional conduct is "prescribing, dispensing or furnishing a prescription medication or a prescription-only device … to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship." A.R.S. § 32-2501(21)(kk) for physician assistants is almost identical. It describes unprofessional conduct for PAs as being "prescribing, dispensing or furnishing a prescription medication or prescription-only device … to a person unless the licensee first conducts a physical examination of that person or has previously established a professional relationship with the person.

Physician assistants must have additional approval of their board to write or dispense 14-day prescriptions for controlled substances. State law prohibits a doctor or a PA from prescribing controlled substances to close relatives. This means that neither health care provider may write such prescriptions for a spouse, natural or adopted children, father, mother, brothers and sisters or the same relatives of the spouse. In most of the cases where a violation has occurred, the licensee has also failed to keep adequate medical records on the family member/patient, compounding the offense. The citation for this in the Medical Practice Act is A.R.S. § 32-1401(27)(h) and for the PA Practice Act, A.R.S. § 32-2501(21)(r).

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CALIFORNIA

OPERATION SAFE MEDICINE RETURNS JULY 2009

Effective July 1, 2009, the Medical Board of California reestablished its Operation Safe Medicine (OSM) unit in southern California to target unlicensed activity, corporate practice of medicine, and lack of supervision violations.

Some history: In 2000, there was a growth in unlicensed individuals and unregulated clinics, predominately in southern California. These unlicensed individuals operated from residences or the back of legitimate business locations, and targeted California immigrant health care consumers who were seeking familiar, discreet, and affordable services. These unlicensed individuals usually provided services and dispensed dangerous drugs not manufactured under the Food and Drug Administration guidelines or even approved for use in the United States. These unlicensed individuals lacked qualifications and training, which meant that the health care resulted in the increase of dangerous reactions and infections from faulty diagnosis, untreated disease, health complications, and even deaths.

In July 2000, the board was authorized four investigator positions to establish an unlicensed activity investigative team called Operation Safe Medicine, whose sole purpose was to investigate complaints of unlicensed activity received from health care consumers, and also to work with other regulatory and law enforcement agencies to find unlicensed facilities. In its 2001-2002 Annual Report, the board reported that the number of cases referred by board investigators for criminal action had increased.

The board's OSM was responsible for much of the increase in criminal filings from 58 in Fiscal Year (FY) 2000-2001 to 82 in FY 2001-2002. They reported that OSM had become an effective mechanism for dealing with unlicensed activity and the so-called backroom clinics in the Los Angeles and Orange County areas. Several criminal investigations conducted by OSM investigators had resulted in the filing of felony and misdemeanor charges against unlicensed individuals treating various medical conditions.

Shortly after, due to budget shortfalls that resulted in vacancy reductions and vacancy sweeps in FY 2002-2003, the established OSM positions were transferred to the board's enforcement units to maintain minimum staffing levels in other units. This unfortunately resulted in the closure of OSM.

As a consumer protection agency, the board's mission is to protect health care consumers through proper licensing and regulation of physicians, surgeons, and certain allied health care professionals through the vigorous, objective enforcement of the Medical Practice Act. It is also responsible for enforcing the disciplinary decisions it renders. Board decisions are varied and complex, and require specialized medical-legal expertise to ensure physicians comply with the terms and conditions ordered. Federal, local, and private organizations do not possess the medical-legal expertise required to ensure compliance with provisions of the Medical Practice Act.

Ultimately, at the November 2007 board meeting, the members approved the re-establishment of OSM, and the dedication of staff to the enforcement of laws relating to the unsafe practice of medicine in California, including, but not limited to, the various use of lasers for cosmetic procedures.

The following are some examples of the more egregious types of unlicensed cases that the new OSM will target:

- An unlicensed female operating a booth at an indoor swap meet was dispensing and administering various prescription drugs, non-prescription drugs, and herbal remedies from another country. She injected a female with a substance labeled as eucalyptus oil in the bathroom of the swap meet and the victim died the following day at her residence.
- An unlicensed male was performing breast augmentation surgery on females in an unlicensed facility; the victims suffered severe infections and disfigurement of their breasts.
- An unlicensed female injected corn oil into the victims' buttocks as a means of cosmetic enhancement; one female victim almost died from a fat embolism.
- An unlicensed individual was using unapproved Botox and industrial grade silicone on health care consumers.
- An unlicensed female was injecting victims with household silicone, resulting in infections and disfigurement.
- An unlicensed female operated a "medical clinic" where she performed intense pulsed light laser therapy for removal of excess fat and stretch marks, and treatment of skin conditions and broken capillaries; victims were injured.
- An unlicensed male was conducting physicals and administering vaccinations as part of the immigration process; the physicals were not properly conducted and the vaccines were saline injections, thereby potentially exposing the California population to previously controlled and/or eradicated diseases.
- An unlicensed individual burned a victim with a laser treatment at a laser clinic that had insufficient supervision.
- An unlicensed individual permanently branded a victim using the wrong device, instead of removing a tattoo.

- An unlicensed individual permanently scarred a victim who received laser treatment on a red vein, with a device designed to treat blue veins.
- An unlicensed individual permanently de-pigmented the skin of a victim who was treated with an incorrect device.

With the re-establishment of the board's Operation Safe Medicine, California health care consumers will be better protected from various unsafe and unlicensed practices of medicine.

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COLORADO

MEDICAL BOARD IMPLEMENTS PHYSICIAN PROFILE REQUIREMENTS

The Colorado Board of Medical Examiners has implemented the requirements of the *Michael Skolnik Medical Transparency Act*, which was enacted into law by the Colorado General Assembly in 2007. The *Act* requires all physicians who submit an application for an initial license, license reinstatement or reactivation, on or after January 1, 2008, to disclose specific information that can be accessed by the public. The *Act* requires that the following information be disclosed to the public:

- Name
- Aliases
- Current Address
- Telephone number
- Information regarding all medical licenses ever held
- Current Board Certifications
- Practice Specialties
- Affiliations with hospitals and health care facilities
- Current ownership interests in businesses
- Current employment contracts
- Public disciplinary actions against a medical license
- Agreements and Stipulations to temporarily cease medical practice
- Involuntary hospital or health care facility privileging actions
- Involuntary surrender of a DEA registration
- Criminal convictions or plea arrangements for felonies and crimes of moral turpitude
- Judgments, settlements and arbitration awards for medical malpractice claims
- Refusal by an insurance carrier to issue medical liability insurance

Physicians will create their profiles using an online system and the information will be made available to the public through the board's website. Affirmative responses to the questions regarding disciplinary actions, temporary cessations of practice, surrender of DEA registration, criminal convictions and insurance refusals will require the physician to submit specific documents to the board.

Those documents will then be scanned and made available to the public as part of the physician profile. The board encourages physicians who will need to submit such documents to begin gathering them now so they are easily available for submission at the time of license renewal.

The *Act* as well as the rules, policies and updates are available on the board's website or copies can be requested from the board office. It is strongly recommended that physicians read the rules and policies carefully and retain them as a reference to be used at the time of license renewal. Also, note that your profile must be updated within 30 days of the effective date of any reportable action and not just during the renewal period. Physicians are also encouraged to periodically check the board's website for new information regarding the implementation of this legislation. Any questions regarding these requirements should be directed to Physician.Profiles@dora.state.co.us or (303) 894-5942.

ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

The Colorado State Board of Pharmacy is pleased to announce the availability of its Electronic Prescription Drug Monitoring Program (PDMP) at www.coloradopdmp.org.

This program provides a database of controlled substance prescriptions that have been dispensed by Colorado pharmacies and from nonresident pharmacies that ship prescriptions into Colorado. The purpose of the database is to provide objective information to assist practitioners and pharmacists in providing appropriate treatment for their patients.

The program allows prescribers and pharmacists to gather information about the patients they serve and to ensure that their prescribing and dispensing is appropriate for the circumstances presented. For instance, if a patient is taking OxyContin, the prescriber would be able to review

when the patient was first prescribed the drug, how many providers prescribe for the patient, how often, and from what pharmacies the patient is receiving controlled drugs. The prescriber would also be able to determine the dosages the patient is receiving, and with that information try to determine whether the patient is taking the medication appropriately. The information collected by the PDMP is only accessible to prescribers of controlled substances and pharmacists. While patients may access their own personal data by contacting the program, law enforcement officials may only obtain information specific to an individual by the presentation of a subpoena or court order. The state has contracted with GHS Data Management to administer the database and manage the collection of the data. All information is transferred to and from the database via a secure Web portal or secure file transfer.

To learn more about the program, please visit www.coloradopdmp.org.

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DISTRICT OF COLUMBIA

ACADEMIC DETAILING: DISTRICT TO OFFER PROGRAM FOR PHYSICIANS

The District of Columbia Health Professional Licensing Administration (HPLA) announces it will be coordinating an effort, on behalf of the D.C. Department of Health, to offer an academic detailing program to physicians practicing in the District. The Independent Drug Information Service (iDiS) will focus on providing optimal patient care and disease management resources. iDiS will offer helpful resources and tools so physicians can make the best decisions for their patients about therapeutic benefits, risks and costs.

iDiS develops health resources for patients, so physicians and other health care professionals can help educate patients about the medical and therapeutic decisions they've made, and to help improve adherence to treatment regimens. iDiS is a program provided by the nonprofit Alosa Foundation, which is comprised of physicians and researchers on the faculty at Harvard Medical School. The program will offer evidence-based, non-commercial information about medications and other therapeutic options commonly used in primary care.

The program is wholly financed by the District of Columbia through the Department of Health as mandated by SafeRx (D.C. Law 17-0364, the SafeRx Amendment Act of 2008, Title IV Pharmaceutical Education Sec. 401 "Pharmaceutical Education Program Establishment Act of 2008"), which was passed by the District Council to: address pharmaceutical detailing; require detailers to abide by a code of ethics; and establish a pharmaceutical education program for physicians and other health care providers in the District.

The iDiS team of Harvard-affiliated faculty, physicians and researchers comprehensively evaluate biomedical journals and other data sources to pull together the best available evidence about drug safety, efficacy, and cost effectiveness. They then synthesize this material into convenient, clinically relevant summaries. These materials are presented to physicians in their offices by a team of specially-trained physicians, nurses and pharmacists.

No pharmaceutical companies are associated with this program. Program facilitators will present evidence-based data from the most current medical literature. The materials are written by faculty who accept no personal compensation from any pharmaceutical manufacturer for any purpose.

Each D.C. physician's participation is significant and appreciated. Continuing medical education (CME) credits shall be provided to participating District physicians. The program is free and voluntary. Physicians who are interested in participating in this program should contact iDiS.

Through this, and other efforts, HPLA and the physicians of the District can join together to work collectively to ensure quality care for the citizens of the District of Columbia, and for all of the visitors who come to the nation's capital as well.

Reprinted from the May 2009 issue of *D.C. Board of Medicine*, published by the District of Columbia Board of Medicine.

GEORGIA

LEGISLATIVE UPDATES ON REWRITE OF THE MEDICAL PRACTICE ACT

The Medical Board updated the Medical Practice Act (Title 43, Ch. 34) this legislative session. The bill was signed by Governor Perdue and is effective July 1, 2009. Changes include the following:

- Increases the number of board member from 13 to 15 to help with ever increasing workloads
- Changes the Board's name from "Georgia Composite State Board of Medical Examiners" to "Georgia Composite Medical Board"
- Gives the Board authority to order mental and physical examinations for all license groups
- Changes the title of the board president to board chairperson
- Requires individuals to notify the Board within ten days of conviction of a felony
- Adds language to allow medical assistants to give injections under supervision
- Eliminates provisional licenses for physicians
- Eliminates the requirement to register medical licenses with the county clerk, and for the county clerk to report registrations to the board
- Removes the apostrophe from the word "physician's" in the new title "physician assistant"
- Updates the definition of job description, physician assistant, and supervising physician
- Increases the fine from $1,000 to $5,000 for failure to obtain a license prior to practice
- Authorizes PAs and APRNs to pronounce death if so delegated by a physician and identified in job description (PA) and protocol agreement (APRN)
- Makes it unlawful for a physician to be an employee of the physician assistant whom he supervises. (Will grandfather existing relationships as approved by the Board)
- Eliminates the 18-month temporary permit for respiratory care professionals
- Shortens the late renewal period from two years to three months for Clinical Perfusionist licenses
- Moves disciplinary authority for all professions to Article One
- Provides for the delegation of tasks to polysomnographic technologists under physician supervision

Reprinted from the June 2009 issue of the *Georgia Composite Medical Board Newsletter*, published by the Georgia Composite Medical Board.

CREDENTIALING

Smith v. Pratt,
No. M08-01540-COA-R9 (Tenn. Ct. App. Apr. 22, 2009)

The Tennessee Court of Appeal remanded a negligence action brought by the estate of a deceased former patient against medical service providers for a factual determination of whether a hospital's credentialing of a defendant physician was made in good faith.

On Nov. 20, 2003, Christy Smith underwent surgery performed by Stephen Pratt, M.D., a plastic surgeon, to remove excess skin on parts of her body due to weight loss. About 12 days after the surgery, Smith developed open wounds on her back and thigh. A few days after Dr. Pratt sutured the wounds, Smith complained of pain in those areas and in her calf. Dr. Pratt prescribed Avelox.

Smith thereafter developed shortness of breath and increased pain in her left leg. She visited an emergency room where she was diagnosed with deep vein thrombosis (DVT). Smith later developed a pulmonary embolism.

Following Dr. Pratt's death, Smith sued Dr. Pratt's estate for negligence and Centennial Medical Center for negligence in granting Dr. Pratt surgical privileges. A trial court denied Centennial's motion for summary judgment based on its assertion of qualified immunity, and Centennial filed an interlocutory appeal.

The court of appeal noted that an applicable statute extended qualified immunity to hospitals for credentialing decisions. Although the statute was customarily invoked in cases where a physician challenged a credentialing decision, the statute by its own terms clearly extended immunity from liability to any "patient, individual or organization."

The court of appeal rejected Smith's constitutional challenge to the statute. The constitutional guarantee providing for open courts was not offended where, as here, the state had a substantial interest in establishing such immunity as a means of controlling health care costs and encouraging the retention of medical professionals within the state. Accordingly, the case was remanded for a factual determination of whether Centennial's credentialing decision was made in good faith, without malice, and on the basis of facts reasonably known or reasonably believed to exist.

DEFAMATION

Kipper v. NYP Holdings Co.,
No. 54 (N.Y. Apr. 30, 2009)

The New York Court of Appeals affirmed an appellate division's grant of summary judgment in a doctor's libel action against a publisher concerning an erroneous statement about the revocation of the doctor's license. There was no clear and convincing evidence that the erroneous statement was published with reckless disregard for the truth.

The *New York Post*'s Sunday edition carried a short, eight-paragraph, "rewrite" of a 98-paragraph article taken from the *Los Angeles Times*' wire service. The *Times* article, titled "Harsh Reality of 'Osbournes' No Laughing Matter," described the rock-singer John "Ozzy" Osbourne's allegations that his former physician, David Kipper, M.D., had overprescribed various medications to him during the time that Osbourne starred in a television reality series.

In addition, the *Times* article accurately stated that the California Medical Board had "moved to revoke" Kipper's license due to his alleged gross negligence in the treatment of other patients. But the *Post* article, which appeared under the inaccurate headline "Ozzy's Rx doc's license pulled," contained an error. Despite clearly indicating it was based upon "Los Angeles Times reports," the sixth paragraph of the *Post* rewrite incorrectly stated "the state medical board revoked Kipper's license."

Kipper brought a libel action against publisher NYP Holdings Co. The trial court denied the NYP's motion for summary judgment. The court reasoned that NYP bore the burden of demonstrating that its misstatement regard-

ing the status of Kipper's license was not published with actual malice, i.e., with knowledge of falsity or a reckless disregard for the truth. The appellate division reversed, granting the defendant summary judgment and dismissing the action.

The court of appeal granted leave to appeal and affirmed the trial court's judgment. A reasonable jury confronted with the facts and circumstances presented could not find with convincing clarity that the defendant's erroneous statements were published with actual malice. Rather, the record bespeaks non-actionable mistake or negligence.

EXPERT TESTIMONY

Querry v. Sanders,
No. 06-08-00099 (Tex. App. Apr. 24, 2009) *unpublished*

The Texas Court of Appeal ruled that a patient's expert in a health care liability action was sufficient on standard of care and breach issues but was deficient as to causation.

As Dr. Marian Querry was performing laparoscopic surgery on Peggy Sanders for the purpose of removing Sanders' gallbladder, Querry saw in the laparoscope's field of view a duct in an unusual location and one Querry decided was a cystic duct she was to cut as one of the steps toward the gallbladder's removal. She cut it. Unfortunately, the duct proved to be Sanders'main bile duct.

Sanders brought a health care liability action against Querry alleging Querry's cutting of Sanders'main bile duct ultimately caused Sanders' liver to fail. The trial court denied Querry's motion to dismiss based on the alleged failure to tender an expert report by a qualified physician. Querry appealed.

The appeals court affirmed in part and reversed in part the trial court's judgment. The court found that Sanders' expert, Dr. Stephen Ferney, was qualified to render an expert opinion against Querry in this case. Ferney's report was sufficient on the issues of standard of care and breach but was deficient as to causation because it failed to link the transection of the bile duct to liver failure.

With respect to Sanders' claims of Querry's alleged negligence in failing to discontinue the laparoscopy when she encountered a "variant" in Sanders' anatomy, and failing to use the correct surgical procedure, the appeals court reversed and remanded for a determination by the trial court as to whether an extension should be granted to cure the causation deficiency. Because Ferney's report failed to address Sanders' claim of Querry's alleged negligence in failing to properly identify and isolate the main bile duct before initiating the main procedure, the appeals court reversed the trial court's judgment denying Querry's motion to dismiss and dismissed that claim.

INFORMED CONSENT

Himes v. Gabriel,
No. 475,2008 (Del. Apr. 23, 2009)

Affirming the judgment entered on the jury's verdict in favor of a physician, the Delaware Supreme Court held that there was substantial evidence from which the jury could find that the physician obtained informed consent for the surgery performed.

Christopher Himes sought treatment for sleep apnea and snoring from Timoteo Gabriel, M.D. Dr. Gabriel recommended five surgical procedures. Christopher signed a surgical consent form that listed the recommended procedures. Dr. Gabriel performed surgery on Jan. 29, 2004. Christopher died from post-surgical complications several days later. Sheila Himes filed a medical malpractice action against Dr. Gabriel on behalf of Christopher's estate.

Sheila alleged that Dr. Gabriel did not obtain Christopher's informed consent prior to surgery. Dr. Gabriel allegedly failed to tell Christopher that he could undergo the five procedures at different times rather than having all of the procedures performed during the same surgery (the staging option).

The jury returned a verdict in Dr. Gabriel's favor. The trial court denied Sheila's post-verdict motions and entered a judgment for Dr. Gabriel. Sheila appealed, arguing that the weight of the evidence did not support the jury's finding that Dr. Gabriel obtained informed consent.

The supreme court affirmed the trial court's judgment. Sheila failed to show other physicians would customarily disclose the staging option to their patients under the same or similar circumstances. Dr. Gabriel testified at trial that he disclosed the risks and complications of surgery to Christopher.

Although Dr. Gabriel could not remember whether he told Christopher about the staging option, Dr. Gabriel testified

that he did not believe that staging the procedures was an appropriate alternative for Christopher. Experts for both sides testified that Christopher would not be a good candidate for the staging option because of his anxiety about surgery and the risks in administering anesthesia to Christopher multiple times.

The supreme court noted that the issue of informed consent was factually disputed at trial. The jury, as the finders of fact, properly determined the credibility of evidence and what weight to afford to the testimony presented.

MALPRACTICE

Nazar v. Branham,
No. 04-SC-1015 (Ky. Apr. 23, 2009)

The Kentucky Supreme Court ruled a surgeon is not negligent as a matter of law when he left an object in a patient during the patient's operation. The surgeon also was not liable for the conduct of the hospital's nursing staff during the operation.

Sheila Branham, as executrix of the estate of Roe Branham, alleged that Gregory Nazar, M.D., committed medical malpractice by failing to remove an object from Branham's scalp following surgery. The alleged professional negligence occurred at Norton Audubon Hospital during an operation in which a malignant tumor was removed from Branham's brain. Following surgery, Branham complained of pain in his head, which was initially dismissed as an attendant aspect of his surgery. When the pain continued for several weeks Branham sought further medical attention. Tests revealed a Durahook, a small, metallic object used to hold soft tissues apart during an operation, was left in Branham's scalp. The Durahook was surgically removed from Branham's scalp without further complications.

After his second surgery, Sheila, as executrix of Branham's estate, brought an action against Dr. Nazar, his medical practice and Norton. Sheila alleged that the defendants had committed medical malpractice by failing to remove the Durahook from his scalp after surgery. She further alleged that both Dr. Nazar and Norton were vicariously liable for the nursing staff's failure to remove the Durahook from his scalp. Sheila settled her claims against Norton and the trial court dismissed them, while preserving the claims against Dr. Nazar.

Shortly after this settlement, the trial court denied Sheila's motion for summary judgment. The jury then deliberated and returned a verdict in favor of Dr. Nazar, finding that he had not breached the standard of care. The appeals court reversed the trial court's denial of Sheila's motion for summary judgment. Dr. Nazar moved for discretionary review, asking the supreme court to reinstate the jury verdict in his favor. Sheila cross-moved for discretionary review on the vicarious liability issue. The supreme court granted both motions.

The supreme court reversed the appeals court's judgment and reinstated the trial court's verdict in favor of Dr. Nazar. Leaving a foreign body in a patient raises an inference of negligence, but the surgeon may introduce proof that he complied with the standard of care. Once this has occurred, the jury may then decide whether the surgeon met the standard of care. In the present case, Dr. Nazar presented adequate evidence both before and during trial that created fact issues sufficient to defeat Sheila's motions.

The supreme court also determined that the jury should have been permitted to address Dr. Nazar's vicarious liability for Norton's nursing staff during Branham's operation. The evidence suggested that Dr. Nazar lacked the authority to control the details of the nurses' work, their training and terms of employment, and that they were not his agents during Branham's surgery. As a result, the trial court correctly concluded that Sheila was not entitled to judgment as a matter of law on her vicarious liability theory.

PROFESSIONAL MISCONDUCT

Osman v. S.C. Dep't of Labor,
No. 26641 (S.C. Apr. 27, 2009)

The South Carolina Supreme Court affirmed a medical board's issuance of a public reprimand to a physician for deviations from the standard of care in connection with the performance of a surgical procedure.

Hibah Osman, M.D., following an administrative proceeding, received a public reprimand from the state board of medical examiners for conduct in performing a Caesarian section delivery. An administrative law judge upheld the ruling, and Dr. Osman appealed.

The supreme court concluded that the evidence presented supported the board's determination. The record indicated that Dr. Osman agreed to perform the surgery in a community county hospital that lacked adequate blood products

and surgical backup. Severe bleeding during the operation required the patient's emergency transport by helicopter to a university hospital, where a total abdominal hysterectomy was performed.

The supreme court noted the board limited its findings of misconduct to three deviations from the standard of care to which Dr. Osman admitted. Dr. Osman's contention that a public reprimand was not warranted because no allegation was made of an ethical violation was rejected as unsupported by applicable law. Accordingly, the ALC's determination was affirmed.

WRONGFUL DEATH

McDonald v. Mem'l Hosp. at Gulfport,
No. 07-CA-1743 (Miss. Apr. 30, 2009)

The Mississippi Supreme Court affirmed a trial court's grant of summary judgment in favor of a physician and hospital in a malpractice action brought by the surviving spouse of a deceased former patient.

On Mar. 7, 2003, Janella McDonald was admitted to Memorial Hospital at Gulfport (MHG) with pneumonia. A week later, he was transferred to Select Specialty Hospital, where on Mar. 24, 2003, he experienced nausea and vomiting of brown material or blood. Juan Teran-Benitez, M.D., attempted to perform an esophagogastroduodenoscopy (EGD). During the procedure, foreign or coffee-ground-appearing material was encountered.

Because McDonald had do-not-resuscitate status, Dr. Teran-Benitez consulted with his wife, Naomi McDonald, about insertion of an endotracheal tube to protect her husband's airway. Naomi refused, and McDonald expired in the endoscopy lab.

Naomi sued Dr. Teran-Benitez, MHG and numerous medical service providers for wrongful death and malpractice. A trial court granted summary judgment in favor of the defendants, and Naomi appealed.

The supreme court noted that although Naomi offered evidence supporting his claim that the applicable standard of care was breached, none of her three medical expert witnesses addressed the issue of causation. As a result, the trial court did not err in granting summary judgment in favor of MHG based on a finding that Naomi failed to raise a fact issue as to causation.

The Supreme Court further concluded that Naomi's expert medical witnesses were not qualified to testify regarding the standard of care applicable to Dr. Teran-Benitez. The offered witnesses included two pathologists, one of whom also is a psychiatrist.

The Supreme Court concluded that the record supported the trial court's finding that neither expert had experience or familiarity with the standard of care applicable to Dr. Teran-Benitez as a gastroenterologist. Accordingly, the trial court's grant of summary judgment in favor of Dr. Teran-Benitez and MHG was affirmed.