AHRMNY
The Association for Healthcare Risk Management of New York, Inc.

The Risk Management Quarterly

SPRING 2014

In This Issue

PRESIDENT'S MESSAGE

Dear AHRMNY members,

Our June 6th Annual Conference was extremely successful and well attended with 130 attendees!

Gehan Soliman and the Education Committee assembled an annual conference which included keynote topics of Violence in Hospitals and Emerging Trends and the Future of Enterprise Risk Management. The morning and afternoon breakout sessions included Disclosure Communication, Simulation in Healthcare, Worker Safety & Patient Safety in the Age of ACO's--The "New" Safety Crisis and E-Discovery. Overall, the intriguing speakers on these evolving topics in healthcare risk management and patient safety have proven to be very informative for our attendees. Many thanks for the support of our sponsors, contributors and exhibitors of our event. I truly appreciate everyone's hard work for this event as well as throughout the year.

The Association's Board of Directors and committee members have demonstrated a strong commitment to the organization's mission and vision. For this, we are pleased that the dedication of the Board and its committees served as a driving force for progression of the organization.

The Public Relations Committee continues with the commitment and hard work needed to enhance our redesigned website and continue efforts to facilitate communication among our members and with ASHRM affiliated chapters.

Through the efforts of Alvin Safran, Past President and Chair of the Membership Committee, a proposal for an Emeritus Designation was introduced and recently approved by the Board of Directors. We are extremely pleased to announce that Robin Maley, Pamela Monastero, Samuel Senders, Margaret Sullivan and Carolyn Reinach Wolf have accepted an invitation to the Emeritus Designation. All of our mentioned Emeritus Board members have served in the role of President for our Association and are deemed subject matter experts in the healthcare risk management, patient safety, legal and structured settlement communities. We thank them for their years of dedication to the organization and we are truly looking forward to working with them in the future.

As a reminder, the Association's membership campaign begins on July 1st. We encourage members as they renew their membership to think about the areas that interest them and consider joining a committee.

Our Publications Committee has continued to raise the bar with our outstanding Risk Management Quarterly (RMQ) publications that are timely, informative and serve as an enlightening resource for our members. We welcome submissions on risk management and patient safety topics for consideration in this wonderful publication.

The Fundraising Committee worked tirelessly to obtain sponsors, contributors and secure financial support for the organization in order to provide the deliverables to our members. We are extremely indebted to the leadership of the committee and its members. As well, we are appreciative to our generous sponsors and contributors, whose support is essential for the events and opportunities for our organization. Without their consideration and generosity, these events would not be possible.

Our Finance and Bylaws committees have also been hard at work with an ongoing process throughout the year to ensure that AHRMNY operates within its governance and with a timely budget.

In closing, thank you to the Association's members and the Board of Directors for the support during my tenure as President. Wishing you and yours a safe, enjoyable spring and summer season!

Warmest regards,

Francine A. Thomas, President
July 1, 2013 June 30, 2014

EDITOR'S CORNER

The Risk Management Quarterly (RMQ), the official journal of the Association for Healthcare Risk Management of New York, Inc. is published four times a year.

RMQ's Mission Statement: To enhance the quality of healthcare delivery through education, research, professional practice, and analysis specific to risk management issues.

This journal contains articles on a wide variety of subjects related to risk management, patient safety, insurance, quality improvement, medicine, healthcare law, government regulations, as well as other relevant information of interest to risk managers. The articles are usually written by ***AHRMNY*** members, so the journal serves as an opportunity for members to showcase their writing talents.

Click here for the official ***RMQ*** Author Guidelines
http://67.43.15.6/images/downloads/Newsletters/author_guidelines_7_2009.pdf

Reminder:

Maximum article length 3,500 words

Photo requirements: (high resolution JPEGs – at least 300 dpi)

AHRMNY will not publish those articles promoting products or services

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The information presented in
THE RISK MANAGEMENT QUARTERLY
is for educational purposes only

WE WANT TO HEAR FROM YOU FOR THE SUMMER AND FALL EDITIONS

We are asking our readers to submit articles for the summer and fall 2014 editions of the ***RMQ*** that focus on patient safety, environmental or staff safety, risk management, claims management, insurance issues and other relevant topics.

RMQ is published four times a year with a distribution of approximately 300 copies per quarter. Please forward any ideas or submissions for publication in the ***RMQ*** to "**Editors**", via email with attachments to: ahrm@optimum.net.

The deadline for submission and consideration for the next journal is **August 15, 2014.**

The Association for Healthcare Risk Management of New York, Inc. (**AHRMNY**) is the NY Chapter of the American Society for Healthcare Risk Management (ASHRM), a personal membership group of the American Hospital Association (AHA). AHRMNY is a non-profit, 501(c)(3) educational organization incorporated in NY and governed by its elected officers and directors.

Membership is comprised of those individuals who are either regularly involved in or who are interested in the risk management and/or patient safety areas of a healthcare organization. Our members include persons with interest in healthcare risk management from many areas, including: Hospitals, Long Term Care Facilities, Law Firms, Insurance Companies, Third Party Administrators, Brokerage Firms, Consulting Organizations, and other health care settings. This diversity makes a variety of viewpoints available to members and contributes to the vitality of the organization.

AHRMNY membership has been approximately 300 over the last three years. Many of our members are also members of the national organization, ASHRM. We provide an excellent opportunity for keeping up to date on current risk management topics and networking with your peers. Membership dues are currently $100 a year. We offer an organizational discount of $250 for three members all from the same company. Students can join AHRMNY for only $50 a year and non-metropolitan area members can join at a reduced rate of $50. Please contact Membership Committee at (973) 641-5311 or ahrm@optimum.net with any questions pertaining to membership.

Benefits of Joining

Each year we will hold at least three educational sessions of which one is a full day session. The full-day session (and annual meeting) is held each June. A fee may be required to attend. In addition there may be one or more networking/educational event(s) with a keynote speaker when members may be required to pay a fee to attend.

Our journal, ***The Risk Management Quarterly***, free to members, is published regularly. It contains scholarly articles, reviews of lectures and other presentations on a wide variety of subjects related to risk management, insurance, patient safety, law and governmental regulations as well as event notices and other information of interest to members. The articles are usually written by AHRMNY members, so the newsletter also serves as an opportunity for members to exercise their writing talents.

If you have already renewed membership please encourage a colleague to join.

THE HAZARDS OF PHARMACEUTICAL DISPOSAL: AN ARISING RISK FOR HEALTHCARE

By Suzanne M. Avena, Esq., and Dayna B. Tann, Esq.

Description of The Issue

The presence of pharmaceuticals in our nation's waterways arise from a variety of sources, particularly health care facilities. This fact has recently brought the topic of pharmaceutical waste disposal to the forefront of environmental and public health risk issues. New science indicates that the prior practice of discharging non-hazardous waste pharmaceuticals down the drain, while generally accepted and legal, is contaminating our waterways. Although harmful chemicals can enter water sources through various means by the general population, because of the quantities of pharmaceuticals used and disposed at hospitals and long term care ("LTC") facilities, the health care industry in particular is being examined to reevaluate the legal practice of flushing or pouring unused pharmaceutical products directly into sinks or other drains. From there, these products typically flow into municipal sewage treatment plants or septic systems which have been discovered to be non-equipped to remove all pharmaceuticals. The result is that these medications, including the multitude of anti-depressant and hormone disruptors that are being used with greater frequency by the nation's general population, are filtering into our waterways. Accordingly, state regulatory agencies as well as local governments are now seeking to enact stricter environmental laws governing the disposal of these pharmaceuticals.

Wastes typically disposed of by healthcare facilities consist of pharmaceuticals as well as their related contaminated packaging. These include prescription and over-the-counter medications, nutraceuticals, hormones, anti-depressants and biopharmaceuticals. These disposed pharmaceuticals can fall into several different legal categories of waste under Federal and State laws and regulations. The majority of these substances fall into the category of non-hazardous or regulated medical waste. However, only about five percent of the pharmaceutical waste stream is regulated as hazardous waste and another five percent as controlled substances. Each of these waste categories have specific and differing regulations that apply to their management and disposal, which is causing confusion and risk. Proponents of change to these existing laws contend that although priority should be given to the management of hazardous pharmaceutical waste and controlled substances, this should not preclude implementation of adequate procedures for the management of non-hazardous pharmaceutical waste.

Hazardous wastes are generally defined and regulated under the Federal Resource Conservation and Recovery Act (RCRA) and certain New York State analog solid and hazardous waste management laws.[1] RCRA therefore controls the management and disposal of hazardous pharmaceutical wastes and ensures they are managed in an environmentally sound manner. Under RCRA a waste is considered 'hazardous' if specifically listed as such by the EPA or if it exhibits one or more of the specified characteristics required to render it as hazardous under its provisions, such as ignitability, corrosivity, reactivity and toxicity.[2] Certain frequently used pharmaceuticals, such as physostigmine (for glaucoma and Alzheimer's disease) and warfarin (a blood thinner) are identified and listed as hazardous waste under Federal and New York State regulations.[3] However, RCRA regulations have not been substantially updated or the hazardous waste list added to since RCRA was enacted in 1976.[4] Some pharmaceuticals such as chloral hydrate (used as a chemical reagent and long ago used as a sedative) are both a hazardous waste *and* a controlled substance. Such hazardous pharmaceutical wastes are subject to hazardous waste generator regulations when under the control of a provider or facility, as well as controlled substance regulations.

Furthermore, under the Federal Clean Water Act, the drain disposal or flushing of hazardous waste is prohibited.[5] Therefore, the flushing of any amount of "P"-listed acute hazardous waste, or more than 15 kg (about 33 pounds) of "characteristic" hazardous waste or "U"-listed chemotherapy waste in a calendar month requires notification to the local publicly owned treatment works, the New York State Department of Environmental Conservation's ("NYSDEC") Director of the Division of Solid and Hazardous Materials, and the EPA's Region 2 Director of the Division of Environmental Planning and Protection. In the case of "P"-listed waste, the notification to these agencies must include a certification that a program is in place to reduce the volume and toxicity of hazardous waste generated to a degree determined to be economically practicable.

Pharmaceuticals That Are Regulated Medical Waste

Pharmaceutical wastes such as discarded prescription serums, vaccines, antigens and antitoxins that are made with living organisms, and the medicine vials containing these biologicals, as well as the syringes to which a needle (used or unused) or other sharp is attached to administer such injectables, are considered regulated medical waste (RMW). These wastes must be managed and disposed as RMW under applicable New York State law.[6]

Pharmaceutical Wastes That Are Controlled Substances

The Federal Controlled Substances Act (CSA) controls the disposal of controlled substances. The CSA consolidates numerous laws regulating the manufacture and distribution of prescription drugs such as narcotics, opiates, stimulants and chemicals used in the production of controlled substances. Entities registered with the DEA under the CSA may dispose of harmful controlled substances through several permitted means, including returning unused products to manufacturers through reverse distribution or through destruction in accordance with applicable State law, which usually includes on-site witnessed destruction, including flushing (except the flushing of hazardous waste which is prohibited by the Federal CWA, as noted above).[7]

In New York State, the Department of Health ("NYSDOH") Part 80 Rules and Regulations on Controlled Substances sets forth the requirements for disposal of controlled substances by entities *registered* by the Federal Drug Enforcement Administration ("DEA"), as well as those *licensed by* the NYSDOH. Section 80.51 of Part 80 requires that NYSDOH approve the manner and detail of all such disposal pursuant to a written request. Controlled substances must be rendered totally "unrecoverable and beyond reclamation" when disposed, in order to avoid diversion. Up to now, the most common permitted method of destruction has been flushing. However, facilities that are *not registered* with the DEA or licensed with the NYSDOH, but instead take possession of a patient's controlled substances for the purpose of safeguarding and administering the medications pursuant to a Class 3A Institutional Dispenser Limited license, are not allowed the disposal options as mentioned above.

Efforts to Address Gaps in Regulations for Disposal of Pharmaceuticals

Thus, there is a lack of definitive regulations on both the Federal or State level with respect to the proper disposal of certain pharmaceutical wastes. Regulatory agencies fear that the lack of a cohesive and coherent policy will lead to a further contamination of waterways of many pharmaceuticals of concern, such as hormones, antibiotics, antidepressants, antihypertensive and other powerful drugs. As a result, the Environmental Protection Agency ("EPA"), the NYSDEC and the NYSDOH, as well as local governments, are actively reviewing existing policies governing the disposal of pharmaceutical wastes, as well as other hazardous and potentially hazardous chemicals, particularly as they pertain to hospitals and healthcare facilities.[8] In the absence of definitive new regulations, in some cases where it has been determined that drinking water is imminently threatened, prosecuting agencies have already been requiring certain institutions to implement such practices in advance of the anticipated revisions to existing law.[9]

Reverse Distribution

As previously mentioned, disposal of unused and expired pharmaceuticals by use of reverse distribution is a method aided by companies that track manufacturer return policies and facilitate a return of these drugs for potential credit from the manufacturer. The EPA has approved this method of disposal for close to three decades through two (1981 and 1991) Letters of Interpretation.[10] However, not all products are eligible for credit, depending on the return policies of the manufacturers, which change frequently. Additionally, since most LTC facilities are not DEA registrants (unless they have an on-site pharmacy), they are not eligible to return pharmaceuticals to manufacturers or utilize reverse distributors.[11] Those products which cannot be returned are often thrown away or flushed.

EPA Universal Waste Rule

EPA has proposed an amendment to the Universal Waste Rule which would add hazardous pharmaceutical wastes to the Federal Universal Waste Program.[12] The Universal Waste program is essentially a streamlined management program for certain hazardous wastes designed in part to ease the burden of managing wastes and to promote collection and recycling of commonly generated wastes such as batteries and fluorescent light bulbs.[13] Although the EPA had initially anticipated the amendment would be effective by April of 2011, concerns expressed in response to the proposal with respect to the lack of notification and tracking requirements for facilities handling and transporting universal pharmaceutical wastes have delayed its implementation.[14] In order to properly address these concerns, the EPA has decided to not finalize the 2008 proposed rule, but instead develop another proposal in 2014 for new standards for the management and disposal of hazardous waste pharmaceuticals generated by healthcare facilities. However, the proposed rule will only pertain to those pharmaceutical wastes that are generated by health care-related facilities and that meet the current definition of an RCRA hazardous waste, thereby significantly reducing the universe of included pharmaceuticals.[15] As mentioned before, given that only 5% of pharmaceuticals on the market are considered hazardous under RCRA, this restriction considerably "waters down" the rule.[16] Nevertheless, States are permitted to enforce regulations that are more stringent than the Universal Waste regulations and may promulgate their own rules prohibiting healthcare facilities from flushing unused pharmaceuticals.[17]

EPA "Best Practices" Guidance

The EPA has also conducted a study concerning the 'best practices' for managing unused pharmaceuticals at health care facilities. The study is aimed at understanding the factors which contribute to pharmaceuticals entering the water and has included a focused look at medical facilities which are believed to dispose of the largest quantities of unused pharmaceuticals into water. Generally, healthcare facilities discharge their wastewater to publicly owned water treatment works. However, traditional wastewater treatment is not designed to remove pharmaceuticals. Additionally, while some of the upgraded facilities have more advanced treatment technologies, even these facilities are not specifically designed to remove pharmaceuticals. As a result, significant amounts of pharmaceutical waste passes through without being filtered which results in the waste ultimately passing through into our waterways. Based on these findings, in August 2010, the EPA issued a draft Best Management Practices Guidance Document for managing unused pharmaceuticals at health care facilities.[18] The Guide outlines the steps health care facilities can take to identify and properly manage unused pharmaceuticals including: (i) conducting an inventory of pharmaceuticals and unused pharmaceuticals to quantify the amount of medication the facility disposes; (ii) reducing unused pharmaceuticals by reviewing purchasing practices or using limited dose or unit dose dispensing; (iii) identifying and managing types of unused pharmaceuticals and applicable disposal regulations; (iv) segregating waste for disposal; and (v) training staff in proper disposal methods.[19]

Take Back Programs

On October 12, 2010 the Secure and Responsible Drug Disposal Act of 2010 (the "Disposal Act"), which amends the CSA and provides for the take-back disposal of controlled substances by legitimate users, *i.e.*, patients, was signed into law by the President.[20] Under the Disposal Act, consumers in possession of controlled substances will be authorized to transfer such drugs to a non-DEA registered entity, including another LTC facility, which is authorized to dispose of them in accordance with regulations issued by the U.S. Attorney General, so as to prevent drug diversion.[21]

Importantly, the legislation allows LTC facilities to dispose of controlled substances in accordance with regulations to be promulgated by the Justice Department.[22] The legislation seeks to address existing problems with current laws that prevent patients and LTC facilities, who are not DEA registrants, from effectively utilizing reverse distributors and drug return policies.[23] On December 21, 2012, the DEA published a Notice of Proposed Rulemaking for Disposal of Controlled Substances to govern the secure disposal of controlled substances by DEA registrants and ultimate users.[24] If adopted, the regulations would implement the Disposal Act by incorporating the corresponding regulations into a new section of 21 CFR Part 1317 which pertains to disposal.[25]

Pharmaceutical Disposal in New York

New York, like other states, has undertaken strong initiatives to impose more stringent disposal requirements for pharmaceuticals. In 2009, the Office of the Attorney General ("OAG") ordered several hospitals and nursing homes in the upstate New York watershed area to stop "flushing" pharmaceuticals, including controlled substances, down drains. The impetus for the OAG actions was the discovery of new science indicating that pharmaceuticals may be getting into drinking water.[26] However, further prosecution against other healthcare entities on this issue has since waned as a result of strong political pressure against enforcement actions which tried to effect policy changes beyond current law. Since then, the OAG has been working with other state and Federal environmental regulatory agencies, including the New York Bureau of Narcotics Enforcement ("BNE") and NYSDEC to determine a policy consensus based on current regulations. In 2010, the NYSDEC issued a letter to affected facilities/programs introducing an expansion of its "Don't Flush Your Drugs" campaign in an effort to urge entities to voluntarily reduce the presence of pharmaceuticals in New York State's waters.[27] The "Don't Flush Your Drugs" campaign is designed to keep New Yorkers from flushing pharmaceuticals by raising public awareness about the issue and providing information about how to properly dispose of household pharmaceuticals.[28] By making a similar recommendation to health care providers and facilities that generate pharmaceutical waste, the NYSDEC expanded on this program by targeting the entities that contribute the most to the increasing amount of pharmaceuticals found in our waterways.

Additionally, in August 2010, the NYS BNE released a controlled substance disposal/destruction guidance letter.[29] It provides Class 3A facilities (nursing homes and LTC facilities licensed to dispense limited controlled substances but which do not have pharmacies on site) wider latitude regarding disposal methods for controlled substances, while maintaining drug diversion. Although BNE specifically includes flushing, other methods of disposal/destruction suggested by BNE include incineration at NYSDEC-permitted solid waste incinerators (for non-hazardous controlled substances), surrender of controlled substances to local law enforcement, or collection at pharmaceutical take-back events sponsored by communities and/or the NYSDEC.[30]

Long Island is particularly concerned with the quality of its drinking water. Unlike upstate New York and New York City, which obtain their drinking water primarily from reservoirs, Long Island is a sole-source aquifer region, which means that Long Island residents obtain their drinking water from groundwater.[31] As such, contamination of the groundwater from pharmaceutical waste poses an even more direct threat to the health of Long Island residents. In an effort to reduce the amount of pharmaceutical waste circulating in Long Island's groundwater, both Nassau and Suffolk Counties have set up collection centers at local precincts and organizations, in which individuals have 24/7 access to dispose of household pharmaceuticals.[32] Additionally, in 2011, the Suffolk County Legislature passed a law requiring all Suffolk County hospitals, nursing homes, hospice and long-term care facilities to file an annual plan for the safe disposal of unused and/or expired medications with the Suffolk County Department of Health Services.[33] The plan must set forth the means by which the facility will dispose of such medications in an environmentally safe manner to prevent the medications from entering the drinking water supply, rivers, oceans or other bodies of water.[34] While Nassau County likewise continues to strive to decrease the amount of pollution in its water, Suffolk County may be on the forefront of this issue given that much of Suffolk County uses cesspools and septic systems, whereas Nassau County is mostly connected to the sewer systems.

Conclusion

The issue of proper disposal of pharmaceuticals is complex and has become an increasing cause of concern among the healthcare and environmental communities alike. It is likely that significant changes to existing disposal policies and regulations will be made at both the Federal and State level. In the interim, healthcare entities should focus on reviewing their existing disposal practices and engage environmental legal and consulting professionals to evaluate their current practices which might subject them to enforcement exposure and penalties for violations of existing regulations under either state or Federal laws. To the extent a safer, viable alternative is available for disposal which is in compliance with Federal and State regulations, all efforts should be made to implement alternatives, particularly where flushing is the existing method of disposal. Hospitals and healthcare facilities must be proactive with their disposal policies and enact safer alternatives before the need arises.

Article References Listed on page 24

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ADDRESSING THE PHYSICIAN SHORTAGE

By David N. Hoffman

Baby Boomers, the Nurse Practitioner Will See You Now

We have known for some time that the double hit of the aging of the baby boomer population and the loss to retirement of physicians who are themselves members of the baby boom, would produce a shortage of physicians, at least in certain geographic areas. This comes just as the demand for medical services by the aging baby boom cohort reaching retirement and beyond, requires ever increasing amounts of healthcare services. In 2005 the federal government's Council on Graduate Medical Education (CGME) and the American Association of Medical Colleges (AAMC) first publicly acknowledged what was obvious to researchers for decades; that as we reached the teens of the 21st century, the number of physicians retiring from the practice of medicine would outstrip the number of graduates from medical schools in the United States and abroad, resulting in a physician shortage for a decade or more. Specifically, the CGME reported:

1. Under current production and practice patterns, the supply of practicing physicians in the U.S. is expected to rise from 781,200 full-time equivalent (FTE) physicians in 2000 to 971,800 in 2020, a 24 percent increase. However, growth is expected to slow considerably after 2010, reflecting increased rates of physician separation due to the aging of the current physician workforce and the relatively level annual number of new physician entrants since 1980. After 2015, the rate of population growth will exceed the rate of growth in the number of physicians. The per capita number of physicians is forecasted to rise from 283 per 100,000 Americans in 2000 to 301 in 2015 but then drop to 298 in 2020. Under alternative assumptions regarding physician lifestyle changes (such as hours worked) and increased productivity, the effective supply of physicians (FTEs) may grow to nearly 1.08 million physicians in 2020. The most probable aggregate projection suggests that the supply of physicians will number approximately 1.02 million FTEs in 2020.

2. At the same time, for a number of reasons and under a number of scenarios and models, the demand for physicians is likely to grow even more rapidly over this period than the supply. It is likely that the demand for physician services will grow to between 1.03 million and 1.24 million physicians in 2020. The three major factors driving the increase in demand will be: a) the projected U.S. population growth of 50 million persons (18 percent) between 2000 and 2020; b) the aging of the population, as the number of Americans over 65 increases from 35 million in 2000 to 54 million in 2020; and c) the changing age-specific per capita physician utilization rates, with those under age 45 using fewer services and those over age 45 using more services.

3. The need for services, reflecting primarily the use of services under universal insurance and increased utilization review processes, is also expected to increase over the period. Need is projected to grow to between 1.09 and 1.17 million physicians in 2020.

4. If the Nation's population continues to use services in the future as it has in the past, and if physicians practice in the future as they have in the past, then the Nation is likely to face a shortage of physicians in the coming years.

http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/Reports/sixteenthreport.pdf

The reaction from the American medical school community as a whole has been to slowly, and some argue, inadequately, expand both the number of seats in existing U.S. domestic medical schools, and slightly increase the total number of both allopathic (M.D.) and osteopathic (D.O.) medical schools. At the same time, in response to the obvious business opportunity presented by this looming and now present physician shortage, the growth of the for-profit medical education industry has produced significant expansion in the number of offshore-Caribbean and European medical schools, that have been developed and/or expanded the number of available seats, to address the growing demand for physicians in the U.S.

Thus, the growth in the number of available seats both in domestic and offshore medical schools has failed to keep pace with the need for clinicians to provide care to our growing and aging population. Two recent developments signal the acute awareness by healthcare policy makers in government of the need to take steps immediately that will expand access to care among the baby boom population, as well as among the population of recently insured individuals who now have access to care, some for the first time, due to the Affordable Care Act.

In March the ACGME announced an agreement with the accreditation body for osteopathic residencies, which will take the first step toward eliminating the distinction between osteopathic and allopathic medical residencies. Under the terms of the agreement, all residencies, whether historically accredited by the AMA or the American Osteopathic Association (AOA), would be available to graduates of either group's accredited medical schools. This is a particularly important development because no increase in the number of medical school graduates will do anything to address the shortage of physicians, if those physicians are not able to obtain at least the PGY-1 internship, necessary to obtain licensure. Nearly all physicians upon graduating from medical school seek residency in either: primary care, subspecialty, or surgical specialty disciplines, in order to be able to market their services as specialists or experts in their chosen area of practice. Approximately half of the graduates from "foreign" medical schools are unable to obtain admission to a US residency program.

In announcing the integration of M.D. and D.O. residency programs, Thomas J. Nasca, MD, MACP, Chief Executive Officer of the Accreditation Council for Graduate Medical Education, made the case for cooperation in "*the creation of a single accreditation system to set standards and oversee the education and training of future generations of physicians to serve the American public*", in starkly ethical terms. "The recent agreement between the Accreditation Council for Graduate Medical Education (ACGME), the American Association of Colleges of Osteopathic Medicine (AACOM), and the American Osteopathic Association (AOA) sets in motion the accreditation of all GME programs under the auspices of an expanded ACGME". He stated:

> Those of you who have heard me speak about our responsibilities to the public in the social contract, that has its roots in our voluntary oath to society and each patient we serve, understand the perspective and focus of the ACGME. We in the GME community are responsible for the preparation of the next generation of physicians to serve the public in fulfillment of the profession's responsibility as a Public Trust, as outlined by Percival in 1803, and reaffirmed by, among others, the American Medical Association, and more recently in the American Board of Internal Medicine Foundation Charter on Professionalism and synthesized by McCullough. The ACGME and AOA have fulfilled the oversight role of the educational preparation of the next generation of physicians on behalf of the profession and the public, assuring the quality of the education provided in the GME phase of the continuum of medical education. It is in this context, and with this motivation, that the ACGME embarked upon a path to a single accreditation system in its discussions with AOA and AACOM.

Dr. Nasca concluded by stating that:

A single accreditation system could achieve four significant aims:

- to ensure that the evaluation and accountability for the competency of physicians in graduate medical education programs are consistent across all programs;
- to eliminate unnecessary duplication in the accreditation of graduate medical education;
- to achieve efficiencies and other cost savings for institutions that sponsor "dually accredited" or "parallel accredited" allopathic and osteopathic medical residency programs;
- to enable residents to be eligible to enter all accredited programs in the United States, and transfer from one accredited program to another without being required to repeat training and without causing the sponsoring institutions to lose Medicare funding.

https://www.acgme.org/acgmeweb/Portals/0/PDFs/NascaLetterACGME-AOA-AACOMAgreementMarch2014.pdf (last accessed May 20, 2014).

While these are worthy goals, what remains to be seen is what this new spirit of cooperation will do to motivate CMS to authorize funding of an increased number of GME funded residency slots. The challenge for Hospitals, and particularly for clinical risk managers, will be to efficiently integrate the resulting organizational changes within the medical staff leadership régime, and quickly integrate the modified leadership structure into existing institutional operating procedures. This will be particularly challenging for hospitals that operate both allopathic and osteopathic residency programs.

More recent news in New York State indicates that the solution to the physician shortage may not rest entirely with the physicians. As part of New York State's budget, which was adopted on April 1, 2014, a provision was inserted allowing nurse practitioners to practice independently after they have achieved 3600 hours of experience in practice. This change in licensing requirements, know the Nurse Practitioner Modernization Act (NPMA), will enable nurse practitioners to work side by side with physicians as colleagues rather than subordinate "physician extenders". The conclusion by New York State, that experienced nurse practitioners are competent to provide many primary care level services without physician collaboration agreements, puts New York in the company of 13 other states (AL, AZ, DC, IA, ID, ME, MT, NH, NM, OR, UT, WA, WY) that have taken the same step, as part of a strategy to expand access to care.

Under preexisting law, the only way that a nurse practitioner could maintain an independent practice was through a written collaboration agreement with a duly licensed physician. Under New York State law, each physician was only permitted to collaboratively oversee four nurse practitioners outside the doctor's office. Under this new arrangement for "experienced nurse practitioners" no collaboration agreement is required and nurse practitioners will be allowed to practice within the scope of their training and license, **in hospitals,** in a collegial relationship with physicians.

The new law which was part of the 2014 budget bill (S. 6356—D and A. 8556—D) sets forth the existing standards of practice which remain in effect for "in-experienced" practitioners. Part D of the budget bill provides (new law in Caps):

3. (a) (I) The practice of registered professional nursing by a nurse practitioner, certified under section six thousand nine hundred ten of this article, may include the diagnosis of illness and physical conditions and the performance of therapeutic and corrective measures within a specialty area of practice, in collaboration with a licensed physician qualified to collaborate in the specialty involved, provided such services are performed in accordance with a written practice agreement and written practice protocols EXCEPT AS PERMITTED BY PARAGRAPH (B) OF THIS SUBDIVISION. The written practice agreement shall include

explicit provisions for the resolution of any disagreement between the collaborating physician and the nurse practitioner regarding a matter of diagnosis or treatment that is within the scope of practice of both. To the extent the practice agreement does not so provide, then the collaborating physician's diagnosis or treatment shall prevail.

Paragraph B sets forth the new provisions (in Caps) that apply to Nurse Practitioner with over 3600 hours of practice experience:

[(f)] (B) NOTWITHSTANDING SUBPARAGRAPH (I) OF PARAGRAPH (A) OF THIS SUBDIVISION, A NURSE PRACTITIONER, CERTIFIED UNDER SECTION SIXTY-NINE HUNDRED TEN OF THIS ARTICLE AND PRACTICING FOR MORE THAN THREE THOUSAND SIX HUNDRED HOURS MAY COMPLY WITH THIS PARAGRAPH IN LIEU OF COMPLYING WITH THE REQUIREMENTS OF PARAGRAPH (A) OF THIS SUBDIVISION RELATING TO COLLABORATION WITH A PHYSICIAN, A WRITTEN PRACTICE AGREEMENT AND WRITTEN PRACTICE PROTOCOLS. A NURSE PRACTITIONER COMPLYING WITH THIS PARAGRAPH SHALL HAVE COLLABORATIVE RELATIONSHIPS WITH ONE OR MORE LICENSED PHYSICIANS QUALIFIED TO COLLABORATE IN THE SPECIALTY INVOLVED OR A HOSPITAL, LICENSED UNDER ARTICLE TWENTY-EIGHT OF THE PUBLIC HEALTH LAW, THAT PROVIDES SERVICES THROUGH LICENSED PHYSICIANS QUALIFIED TO COLLABORATE IN THE SPECIALTY INVOLVED AND HAVING PRIVILEGES AT SUCH INSTITUTION. AS EVIDENCE THAT THE NURSE PRACTITIONER MAINTAINS COLLABORATIVE RELATIONSHIPS, THE NURSE PRACTITIONER SHALL COMPLETE AND MAINTAIN A FORM**,** CREATED BY THE DEPARTMENT, TO WHICH THE NURSE PRACTITIONER SHALL ATTEST, THAT DESCRIBES SUCH COLLABORATIVE RELATIONSHIPS. FOR PURPOSES OF THIS PARAGRAPH, "COLLABORATIVE RELATIONSHIPS" SHALL MEAN THAT THE NURSE PRACTITIONER SHALL COMMUNICATE, WHETHER IN PERSON, BY TELEPHONE OR THROUGH WRITTEN (INCLUDING ELECTRONIC) MEANS, WITH A LICENSED PHYSICIAN QUALIFIED TO COLLABORATE IN THE SPECIALTY INVOLVED OR, IN THE CASE OF A HOSPITAL, COMMUNICATE WITH A LICENSED PHYSICIAN QUALIFIED TO COLLABORATE IN THE SPECIALTY INVOLVED AND HAVING PRIVILEGES AT SUCH HOSPITAL, FOR THE PURPOSES OF EXCHANGING INFORMATION, AS NEEDED, IS IN ORDER TO PROVIDE COMPREHENSIVE PATIENT CARE AND TO MAKE REFERRALS AS NECESSARY. SUCH FORM SHALL ALSO REFLECT THE NURSE PRACTITIONER'S ACKNOWLEDGEMENT THAT IF REASONABLE EFFORTS TO RESOLVE ANY DISPUTE THAT MAY ARISE WITH THE COLLABORATING PHYSICIAN OR, IN THE CASE OF A COLLABORATION WITH A HOSPITAL, WITH A LICENSED PHYSICIAN QUALIFIED TO COLLABORATE IN THE SPECIALTY INVOLVED AND HAVING PRIVILEGES AT SUCH HOSPITAL, ABOUT A PATIENT'S CARE ARE NOT SUCCESSFUL, THE RECOMMENDATION OF THE PHYSICIAN SHALL PREVAIL.

SUCH FORM SHALL BE UPDATED AS NEEDED AND MAY BE SUBJECT TO REVIEW BY THE DEPARTMENT. THE NURSE PRACTITIONER SHALL MAINTAIN DOCUMENTATION THAT SUPPORTS SUCH COLLABORATIVE RELATIONSHIPS. FAILURE TO COMPLY WITH THE REQUIREMENTS FOUND IN THIS PARAGRAPH BY A NURSE PRACTITIONER WHO IS NOT COMPLYING WITH SUCH PROVISIONS OF PARAGRAPH (A) OF THIS SUBDIVISION, SHALL BE SUBJECT TO PROFESSIONAL MISCONDUCT PROVISIONS AS SET FORTH IN ARTICLE ONE HUNDRED THIRTY OF THIS TITLE.

http://assembly.state.ny.us/leg/?default_fld=&bn=S06356&term=2013&Summary=Y&Text=Y (last accessed May 20th, 2014)

This change in New York State law and the existing law of the other 13 states moves nurse practitioners more fully into the status created by The Joint Commission (TJC), of Licensed Independent Practitioners (L.I.P.). The Joint Commission recognized many years ago that while physician extenders had their place in the healthcare delivery system, certain clinicians, notably nurse practitioners and nurse midwives were, for all practical purposes, independent clinicians who exercised their own medical judgment and exercised their own judgments about the scope of care that they were qualified and capable of providing. With the removal of the requirement of a collaboration agreement for experienced nurse practitioners, and the inclusion of Hospitals as eligible collaborators, New York is clearly looking to these clinicians to take up some of the slack in seeing the baby boom safely in to their senior years.

The implementation of the Nurse Practitioner Modernization Act promises to be even more challenging for risk managers than the new integrated residency accreditation agreement. Hospital policies and procedures that define the scope of practice for Nurse Practitioners will have to be modified to reflect the new autonomy and responsibility that the N.P.'s have been granted by the new law. Even more sensitive will be the terms of their inclusion in the medical staff structure and the application of the Joint Commission mandated dispute resolution mechanisms to these new professional relationships.

The requirement for mediation of disputes between a Nurse Practitioner and a "collaborating" physician is in some respects a red herring; the nurse practitioner will now be "practicing" as a licensed independent practitioner capacity and will not likely be called upon to routinely clear treatment decisions with the collaborating physician. However the issue of physician input on the scope of a nurse practitioner's practice will be a significant issue, particularly where the presence of nurse practitioners on the hospital/medical staff is a new and perhaps destabilizing phenomena. The way in which a nurse practitioner is credentialed at a particular hospital facility presents the classic risk of over and under inclusive granting of privileges.

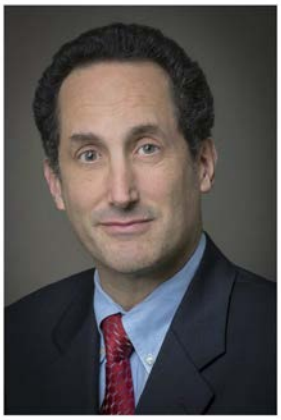
Imagine for a moment if a nurse practitioner is the only clinician on the floor when a patient decompensates, and the introduction of a Swan-Ganz catheter is indicated for management of the patient's hypovolemia or hypotension. If a nurse practitioner is not qualified and capable of performing that catheterization, and is therefore not credentialed to do so, a delay in making that intervention available to the patient should not be considered mismanagement on the part of the hospital. But imagine if the nurse practitioner is trained and experienced in the introduction of a Swan-Ganz catheter, and perhaps was credentialed to perform the procedure at a prior hospital, but at his/her current facility s/he was not, for whatever reason, credentialed to perform the procedure. Under that circumstance a hospital might be well subject to criticism for withholding it's authorization to allow a nurse practitioner to perform a lifesaving procedure, thereby depriving a patient of that intervention on a timely basis. This and related issues concerning scope of practice and overlap in practice between nurse practitioners and physicians is a delicate subject, one which will need to be addressed at the institutional level in order to ensure that the introduction of nurse practitioners, as licensed independent practitioners, expanding access to care, does not become a liability for the institution.

Hospitals would be well advised to draw upon the experience of senior members of their clinical staff who have participated in the integration of midwives into the patient care team. Though midwives are not nurse practitioners, the institutional and cultural experience in the earlier transformation of the clinical care model could be very instructive and provide a template for defining roles and responsibilities.

The NPMA requirement that experienced nurse practitioners, operating without a collaborative agreement with a physician, file a report with the Department of Health on their collaborative relationships is a far more serious matter and one which deserves close attention from all institutions that will offer clinical privileges to experienced nurse practitioners. Because the statute defines failure to prepare such a report as professional misconduct, (therefore making it punishable by the Office of Professional Discipline) it is critically important that institutions inviting nurse practitioners onto their staff closely monitor each NP's compliance with this requirement in a proactive manner. One tracking vehicle that is available to nearly all institutions in New York State is the incorporation of the NPMA reporting requirements into the process for ensuring completion of annual physical exams and renewal of DEA registration. Because of the heightened consequences for failure to comply with this new reporting requirement, it is worthwhile for hospitals to facilitate the filing of those reports on behalf of its staff nurse practitioners. Many hospitals take the same approach to the filing of the annual renewal application for New York State funded excess malpractice insurance coverage. By involving the institution in the reporting process a hospital can provide an added layer of protection against clinician oversight or loss of documents within the state government institutions. Hopefully when the Department of Health creates implementing regulations for the Nurse Practitioner Modernization Act they will create a mechanism for electronic filing of these reports, in the same way it has done so for submission of annual corporate compliance certification to the Office of the Medicaid Inspector General.

We can expect to see a great many more moves by licensing, regulatory and accreditation bodies to address the looming shortage of clinicians, particularly primary care clinicians, as more individuals gain access to the healthcare delivery system and as the quantity and severity of demand for healthcare services increases.

About the Author



David N. Hoffman is a health care lawyer and clinical ethicist at LeClairRyan. He is the former General Counsel and Vice President for Ethics & Compliance at Wyckoff Heights Medical Center in Brooklyn, New York. Mr. Hoffman covers issues and trends in medical commerce for the firm's healthcare blog. For further reading and insights, please visit: http://www.healthlawblog.com

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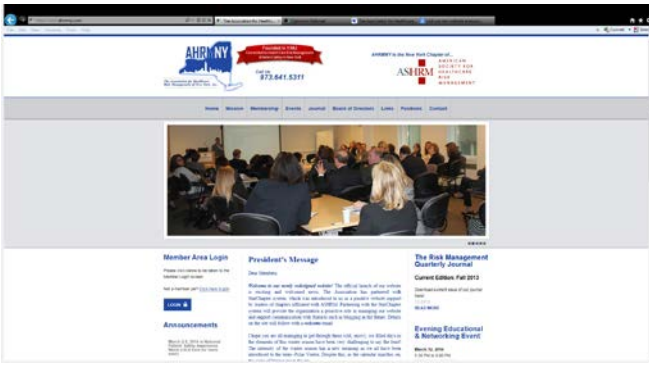

Some benefits of new site:

- Easier job posting process
- Update and personalize your member profile
- View and print past Risk Management Quarterly journals
- View and print handouts from past educational events

Evening Educational & Networking Event Summary

Wednesday, March 12, 2014

Lighthouse International, NYC

AHRMNY's annual evening educational and networking event was held at the Lighthouse International on 59th St. 69 attendees enjoyed cocktails, a buffet dinner and time to catch up and network with colleagues. The educational presentation was delivered by Kathleen Shure, Senior Vice President, GNYHA. Ms. Shure is responsible for all managed care and insurance activities at GNYHA so who better to present to us on "Health Exchange Implementation: How it will Impact Hospitals and Risk Managers". Our speaker aptly described the NY Exchange as *"Travelocity for Health Insurance"* and discussed the challenges and successes of the Federal and NY exchanges. She shared with us that there are now 1 million additional covered lives in NYS. The upside and downside of the Accountable Care Act were thoroughly explored with hospitals waiting to see the ultimate impact of shrinking networks resulting in hospitals and hospital based physicians being non par in numerous plans.

Risky Business

"When Common Sense is Uncommon"

By Pamela Monastero, MBA

COMMON SENSE TIPS FOR STAFF:

I have decided to take a bit of artistic license with this quarter's column. Based on personal experience and 'malpractice' that occurred in a non-medical setting, I thought it would be interesting to focus on how our risk management/safety skills and mind-set predisposes us to think differently from the rest of the world.

By way of background, we recently purchased a home that required extensive renovation – a "gut" job so to speak. Needless to say, anything that could go wrong, went wrong, including the fact that we were scheduled to close during SuperStorm Sandy and our town was flooded, including the bridge. That said, anyone who has undertaken a major home renovation can appreciate the complexities involved.

- *Starting out wrong:* THE GENERAL CONTRACTOR. The 'malpractice' began when we hired a friend as the general contractor (G.C.)—we thought (and he thought) we could save money, which we did but it was not worth the grief. We did not hire a project manager nor did we pay the extra expense to have the architect oversee our renovation project. Our friend the G.C. was to coordinate all aspects of the project with subcontractors, some of whom we independently solicited. The G.C. suffered a marital and financial meltdown during the project and we were left to our own devices and finances--without legal recourse--and we lost a good friend in the process. The project took four months longer than anticipated because he did not hire enough help, thinking he could save us money. Although well intended, it added insult to injury. The G.C. bottom line: this series of bad decisions and missteps cost us time, money and incredible stress. Fortunately, time, patience and finances can fix these sorts of problems—not so, however, when it comes to one's health and well-being.

  Relevance to risk management: THE PRIMARY CARE PHYSICIAN. Not having one good physician coordinate all of your care can cause major and minor oversights from which patient may be unable to recover. For example, my father treats at a well-respected hospital in Manhattan—all of his physicians are there. He suffered from a recent bout of cholecystitis and wanted, of course, to go to a local GI physician in Brooklyn (who happens to have a very good reputation). I recommended that he call his primary care physician (PCP) in Manhattan and have her coordinate his care. His PCP has a terrific track record of referring him to the 'best' physicians and I did explain to my father the importance of having 'one-stop shopping' at a single facility with one physician 'collecting' and analyzing information from specialists and consultants. As seasoned healthcare professionals, risk aversion is hard wired in us and we subconsciously make informed decisions that may be lost on the average consumer. The average person may be unaware of the importance of connecting these dots and thus place greater reliance on their physician(s) and the 'system.' And, as we know, individual providers and the 'system' can often disappoint and fail. By tightly coordinating care through an excellent PCP, the opportunity for mishaps may be greatly reduced.

- *Continuing down the wrong path:* THE PLUMBER. Gross incompetence, inattentiveness, junior and unseasoned staff, and sabotage about sums up our plumbing experience. We had worked with the same plumbing company for 12 years and had wonderful service. Why look for someone else? This was the most difficult lesson to learn because we had a good, solid relationship and a positive experience and could not have anticipated the difficulties that ensued. But, as we all know, even the best people and organizations have problems. At the time of our renovation, our plumber won a huge contract so our job was not his focus. He assigned less experienced staff and one disgruntled staff member (who sabotaged our waste pipe by clogging the pipe, with the result that the rear of the house, which was newly sided, had to be torn down). Multiple plumbing problems ensued—broken ceiling pipes, frozen pipes that threatened to burst, leaking radiators, incorrect supplies, frozen radiators that shut down the heating system and threatened to crack the heating pipes, etc. During the frozen radiator debacle, two of his most seasoned plumbers began to tear down the walls and ceiling in our renovated garage to identify the problem. When the master plumber arrived and saw that the garage was being trashed, he halted the work and identified that a faulty (albeit new) thermostat that they had installed was the source of the big freeze. After sleeping on it, I chastised myself for not utilizing my risk management skills to analyze the situation. The very next day, I highlighted the 'malpractice' in explicit detail for the master plumber. I educated him on what "risk management" is and likened the plumbing experience to a surgeon who does not know what is wrong, does not ask for assistance or consults,

and continues to return a patient to the operating room for exploration. Like the MasterCard® commercials, his expression was 'priceless.' The bottom line: past experience is not always a predictor of the future—our relationship, positive experience and trust in this individual impaired our ability to see what he was doing wrong until it was too late.

***Relevance to risk management**:* THE COWBOY PROVIDER. Anyone who has investigated, defended or pursued an adverse event has encountered the cowboy provider. A cowboy provider is generally arrogant, difficult, of average intelligence and skill, has an exalted view of himself/herself and believes he/she is on their own island. Cowboys are never wrong, never make mistakes, never recognize when their patient is in trouble and certainly never lower themselves to ask for help from a colleague or consultant. The personality and mindset of a cowboy provider predisposes them to miss the obvious, with the result that their patients usually suffer the price. A perfect illustration is post-operative complications. The very first thing any surgeon should consider when a patient's post-operative course is rocky is that something could have gone wrong intraoperatively e.g. anastomatic leaks or breakdowns, misplaced sutures or staples, retained foreign objects, infections, etc. More often than not, there are delays in returning such patients to the operating room, seeking assistance and exploring other options solely because of provider ego. Again, while we as seasoned health professionals would not hesitate to change providers (or facilities) mid-treatment, the average patient/consumer might be reluctant or even frightened to do so, especially if they have a prior relationship with the provider or if the facility is their local community hospital. The familiar is always more comfortable but not necessarily what is best for the patient.

- *Yet another wrong turn:* THE IDENTITY CRISIS. We also learned the hard way that the G.C.'s staff were 'jacks of all trades, masters of none." While they were adept at demolition, framing out the house and putting the 'skeleton' in place, they were not adept at smaller projects and were not true craftsman or 'finishers.' The result: a year later, we are still reaping the 'fruits' of their labor: crooked bath tiles, floors that are not level, 'wavy' ceilings, cracked molding, etc.

  ***Relevance to risk management**:* My aunt was at a local community hospital for a protracted period of time. We started our journey with an ED visit to evaluate a tiny necrotic area on the skin around her ankle. It was debrided in the ED and she was admitted for IV antibiotics and further work up. Although multiple consultants were called, the diagnosis remained elusive thus the appropriate treatment regimen could not be formulated nor the correct antibiotic given. We made the decision to transfer her to a university hospital in Manhattan with a renowned dermatology service. She was immediately diagnosed with pyoderma gangrenosum, which can occur in patients suffering from Crohn's Disease, one of her underlying diseases. While well intentioned, the admitting physician and his colleagues did not have the experience to make this diagnosis. Many local community hospitals provide great care and generally excel in treating routine diagnoses but rare, exotic diagnoses are not their forte. Providers and their respective facilities should know the limits of their expertise and refer cases appropriately to avoid going down the wrong path!

- *Doing your homework/research:* YOUR REPUTATION PRECEDES YOU. Some things did go right. We did research and primary source verification with satisfied consumers before hiring the siding company, the roofer, the central air conditioning company and the skylight installer. These were the only subcontractors that provided excellent service and professionalism.

  ***Relevance to risk management**:* Like most of us, my family's well-being is precious to me. Even highly recommended specialists need to be thoroughly vetted. Sometimes physicians and patients give glowing endorsements of specialists and, occasionally, those endorsements may be based on a provider's personality and charisma and not on reality or outcomes. A physician (specialist) I once worked with was charming and adored by staff and patients alike. He had no known medical malpractice or regulatory issues and, based on these factors (without digging deeper), I transferred my father's care to him. Several years later, my father's COPD was not improving and he continued to have respiratory issues. At this time, a colleague informed me that her father also treated with this provider for many years and that there was a missed diagnosis of lung cancer despite some early warning signs. Needless to say I researched, transferred my father's care to his current provider, who is spectacular, extremely responsive and brilliant!

Dear Risk Manager:

This column, which will appear regularly in the AHRMNY Risk Management Quarterly Journal (RMQ), is designed to support both the novice and seasoned risk manager by presenting brief *pearls of wisdom* based on the experiences of our colleagues. This column is based on the contributions of our constituent members, to whom we are grateful for sharing their experiences. We continue to encourage our members to submit their experiences anonymously for inclusion in this column. Please e-mail any suggestions to pamela.monastero@nychhc.org or mail to AHRMNY utilizing the RISKY BUSINESS form which can be found on our website at http://ahrmny.com/images/downloads/Newsletters/form_risky_business_form_7_2009.pdf. The form permits confidentiality.

LEGAL VERSUS SCIENTIFIC PROOF: THE MISUNDERSTOOD DEFENSE OF PROXIMATE CAUSE

By Rosary Morelli, Esq., and Nathan Schachtman, Esq.

Only recently have attorneys defending medical malpractice cases in New York State begun to file motions and request pre-trial hearings to challenge plaintiffs' underlying scientific claims. New York law, following *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), requires trial courts to determine whether the plaintiff's proposed expert can testify before a jury by first determining that plaintiff's expert's testimony supporting proximate cause is based upon generally accepted methodologies. Epidemiologic studies are often the foundation for proximate cause opinions in medical malpractice cases; however defense counsel often hesitate to examine the underlying epidemiologic data and inferences upon which plaintiff's expert rely to assess whether they meet the *Frye* test.

The elements of a tort require plaintiff to prove that defendant owed plaintiff a duty, that defendant breached the duty, that the breach proximately caused injury to the plaintiff, and that the plaintiff sustained legally recognized damages as a result. In a medical malpractice case, the breach of duty generally requires a showing that the healthcare provider deviated from the standard of care. Proximate cause requires a showing that the deviation can cause the sort of injury sustained (general causation) and the deviation caused this particular plaintiff's injury (specific causation).

The New York legal standard for proximate cause requires that the breach was "more likely than not" a substantial cause of the plaintiff's damages. The medical literature relied upon by plaintiff's expert often involves epidemiologic studies or clinical trials, which are designed, conducted, and interpreted in terms of statistical or probabilistic evidence, which varies in its degree of strength. Weak probabilistic or statistical evidence has been among the key targets for challenges to expert witness testimony in federal court under Federal Rule of Evidence 702 and *Daubert v Merrell Dow Pharms.*, 509 U.S. 579, and its progeny. New York's analogous standard, articulated in *Parker v. Mobil Oil*, 8 N.Y.3d 828 (2007) (following *Frye*) requires general acceptance of the methodology underlying an expert witness's opinion testimony. In the context of disputed proximate causation, *Frye* and *Parker* may require a pre-trial showing that a challenged expert witness's opinions meet the legal standard for showing general and specific causation, with a full exploration of the underlying facts and data upon which the challenged witness relies.

In understanding how these challenges succeed, we can examine toxic tort cases as counsel in those cases traditionally focus on the underlying medical studies to determine if there is sufficient evidence to satisfy the burden of proof on proximate causation between a known causal exposure and a specific plaintiff's injury. A critical element of general acceptance is whether relied-upon studies show a significantly large relative risk to support proximate causation of the individual's injury. As Judge Jack Weinstein wrote 30 years ago, "[a] government administrative agency may regulate or prohibit the use of toxic substances through rule making, despite a very low probability of any causal relationship. A court, in contrast, must observe the tort law requirement that a plaintiff establish a probability of more than 50% that the defendant's action injured him. … This means that at least a two-fold increase in incidence of the disease attributable to Agent Orange exposure is required to permit recovery if epidemiological studies alone are relied upon." In re Agent Orange Product Liab. Litig., 597 F. Supp. 740, 785, 836 (E.D.N.Y. 1984), aff'd 818 F.2d 145, 150-51 (2d Cir. 1987)(approving district court's analysis), cert. denied sub nom. Pinkney v. Dow Chemical Co., 487 U.S. 1234 (1988).

In toxic tort cases, the risk ratio at issue allegedly results from a higher incidence of the disease in exposed persons compared to the incidence in unexposed persons. A similar risk ratio issue occurs in medical malpractice cases when a healthcare provider negligently fails to administer a therapy, or fails to administer a therapy in a timely fashion, to the detriment of the plaintiff. In instances in which the therapy is almost always efficacious, the risk ratio of a bad patient outcome will be very high, and the corresponding probability that the bad outcome would have been avoided by proper or timely therapy will be close to 100 percent. On the other hand, for some therapies, even timely administration is efficacious in only a limited number of cases, less often than the 50-plus percent of cases that would support a proximate cause opinion between the allegedly negligent failure to administer therapy and the patient's bad health outcome.

The language of risk is confusing. Risk is a forward-looking concept. All living persons have a risk of some future disease, which is expressed as a probability. For some people, the risk may be larger or smaller given their genetic makeup, personal lifestyles, or environmental exposures. An individual may have multiple risks of a particular health outcome, and those risks may combine or compete with one another to bring about the outcome. Some risks, such as the gene mutation for Tay Sachs disease are necessary and sufficient for the disease outcome. When we see a case of Tay Sachs, we know that the gene mutation was the cause. Before the disease manifests in the child, we say the child is at risk for developing the disease; but the risk is absolutely predictive of outcome because when the child has the gene mutation the child will have Tay Sachs. Some individuals may have a risk, but that risk is not absolute, and it may never materialize. For example, all smokers are at risk for lung cancer but not all smokers get lung cancer. Alternatively, several risks for the same outcome may be present, and each may be independently sufficient to bring about the outcome.

Causation is a different concept from risk in that it looks backwards from an outcome to antecedent causes that were actually involved in a causal pathway from cause to effect. When a person had several risks, and the related outcome occurs, it may not be obvious which risk or risks participated in bringing about the outcome, and thus qualify to be causes in the specific case.

The prior existence of a risk thus does not translate into an inference of causation in a specific case unless the risk is absolute, virtually 100 percent, such as the genetic mutation in Tay Sachs disease. Most risks are less than absolute even when there is no doubt that in some cases the risk participates in bringing about the disease. Everyone has a small risk of lung cancer, but smokers have a vastly increased risk of the disease. Other environmental exposures also are known or suspected to cause lung cancer, and thus may be risks in a given case. When a patient develops lung cancer, it is no easy matter to look back to identify which risk, or risks, actually participated in causing his cancer. The cancer may have arisen from the baseline risk that everyone has, or from the small risk of an environmental exposure, or from the very large risk of having smoked cigarettes, or from some combination of risks. Inferring causation from a small increased risk in isolation is difficult if not impossible; whereas inferring causation from a very large risk such as that created by smoking for lung cancer will be correct, on a probabilistic basis, the great majority of the time.

The size of a risk is usually expressed as a risk ratio, usually a relative risk that compares the rate of new disease cases in a given time period (incidence) in people with an exposure or lifestyle or gene of interest to the rate of new cases in persons without the exposure. Typically an epidemiologic study or clinical trial follows exposed and unexposed persons prospectively over time. The rate in the exposed divided by the rate in the unexposed is the "relative risk." A relative risk of 1.0 signifies no difference in the outcome in the two groups with respect to the measured exposure. If the relative risk is greater than 1.0, then there may be some role of the exposure in increasing the risk. If the relative risk is less than 1.0, then the exposure may be decreasing the rate of the disease. Regardless of the measured relative risk, scientists will still have to evaluate whether the difference may have resulted from chance or an invalid comparison in the study.

The odds ratio is a similar measure that results from a study conducted retrospectively. In a study of tissue plasminogen activator (t-PA) and stroke outcome, for instance, scientists would compare patients with good outcomes with those who had poor outcomes, and look back to see who had received t-PA within the therapeutic time window. The odds of exposure in the good outcome patients divided by the odds of exposure in the poor outcome group provides the odds ratio, which approximates the relative risk. Suppose we had a study that compared survival in two groups of 200 stroke patients, those who had received t-PA and those who did not. In the group that received the therapy, 130 survived; in the comparison group without the t-PA, 100 survived. The relative risk of survival was increased in the therapy group by 30 percent, for a relative risk of 1.3. If, as is the case, there is no way to tell who among the 130 survivors in the therapy group got a benefit from the therapy and who would have survived regardless of the therapy, we are left with an inferential puzzle. How can we tell who benefited? The probability of any one patient's having benefited from the therapy would be about 23 percent (0.30/1.30), which is way less than the usual requirement of "more probable than not" for civil actions of greater than 2.0.

Small increased relative risks may, in some instances, be real reflections of a causal relationship between the exposure and the outcome, but the small size of the risk may leave us unable to say whether the risk participated in producing an outcome in a specific case. The proof required in the scientific community is not the same proof required in a courtroom. For example the medical community administers t-PA because the scientific proof is sufficient for treatment of all patients. However, the scientific proof has been found not to be sufficient for a plaintiff's expert to testify that the failure to administer t-PA caused a particular plaintiff's injury.

Admittedly the probabilistic arguments concerning proximate cause in cases involving epidemiologic evidence can be difficult to present in understandable terms. A pre-trial *Frye* hearing, however, is an excellent opportunity for defense counsel to educate and persuade the trial court of the inadequacies and analytical gaps in the alleged scientific evidence underlying the plaintiff's expert's opinion.

A litigated case will illustrate the value of seeking a potentially dispositive, pre-trial *Frye* hearing on a proximate causation issue. Returning to t-PA, the most commonly used clot-busting drug administered to ischemic stroke patients, a recurring malpractice claim involves the alleged failure to administer t-PA. The Food and Drug Administration approved t-PA for use in 1996, as it can substantially reduce neurological damages if administered within three hours of stroke onset. Even if administered within the therapeutic time window, however, t-PA will benefit only about 30 percent of patients, and there is no medical "fingerprint" that identifies who has benefitted from the t-PA. In *Samaan v. St. Joseph Hospital*, 670 F.3d 21 (1st Cir. 2012), the First Circuit found that the risk evidence fell short of what is required by Federal Rule of Evidence 702, and the "more likely than not" standard.

Mr. Samaan, the plaintiff, suffered an ischemic stroke, and was treated by the defendants, St. Joseph Hospital and Dr. David Kaplan. Defendants did not dispute that they did not administer t-PA to plaintiff even though they could have given him the treatment within the prescribed three-hour time period. Plaintiff claimed this failure to administer t-PA deviated from the standard of care. The plaintiff's causation expert witness, Dr. Tikoo, opined that the defendants' failure to administer t-PA caused plaintiff's neurological injury. Dr. Tikoo's opinions, as well as those of the defense expert witness, were based in large part upon data from a study done by one of the National Institutes of Health: The National Institute of Neurological Disorders and Stroke t-PA Stroke Study Group, "Tissue Plasminogen Activator for Acute Ischemic Stroke," 333 *New Engl. J. Med.* 1581 (1995), the authoritative randomized clinical trial for the use of t-PA for ischemic stroke.

Both the district court and appellate courts noted that the problem with Dr. Tikoo's opinions lay not in his credentials, the reliability of the data, or the generally accepted view that t-PA can, under certain circumstances, mitigate the sequelae of ischemic stroke; rather the problem lay in the analytical gap between those data and Dr. Tikoo's conclusion that the failure to administer t-PA caused Mr. Samaan's stroke-related injuries. In other words, there was no dispute that general causation existed as the findings of the scientific community established a cause and effect relationship between the administration of t-PA and the mitigation of neurological sequelae; rather the problem was proving specific causation, whether Mr. Samaan would have benefited from the administration of t-PA had he received it.

The district court held that Dr. Tikoo's opinion failed to satisfy the requirements of Rule 702, which states, in part, that the expert may testify if his testimony "is a product of reliable principles and methods; and the expert has reliably applied the principles and methods to the facts of the case." The appellate court agreed that Dr. Tikoo's opinion was inadequate. Dr. Tikoo examined risk ratios from the NIH study, and others, and concluded that a patient's chances of improved outcome after stroke increased 50% with t-PA, and thus the defendants' failure to provide t-PA caused his poor post-stroke outcome. The appellate court rejected the inference from such a low risk ratio to specific causation: "Dr. Tikoo's first analysis depended upon odds ratios drawn from the literature. These odds ratios are, as the term implies, ratios of the odds of an adverse outcome, which reflect the relative likelihood of a particular result. Dr. Tikoo opined that the plaintiff more likely than not would have recovered had he received the drug." Dr. Tikoo incorrectly used the odds ratio to opine that the plaintiff in particular would have recovered if he had been given t-PA by the defendants.

The appellate court identified Dr. Tikoo's mistake as inferring specific causation from the relatively low odds ratio for t-PA of about 1.5, established by the scientific literature. The Court focused in on this gap between risk and causal attribution in an individual's case:

> [Dr. Tikoo's] reasoning is structurally unsound and leaves a wide analytical gap between the results produced through the use of odds ratios and the conclusions drawn by the witness. When a person's chances of a better outcome are 50% greater with treatment (relative to the chances of those who were not treated), that is not the same as a person having a greater than 50% chance of experiencing the better outcome with treatment. The latter meets the required standard for causation; the former does not. To illustrate, suppose that studies have shown that 10 out of a group of 100 people who do not eat bananas will die of cancer, as compared to 15 out of a group of 100 who do eat bananas. The banana-eating group would have an odds ratio of 1.5 or a 50% greater chance of getting cancer than those who eschew bananas. But this is a far cry from showing that a person who eats bananas is more likely than not to get cancer.
>
> Even if we were to look only at the fifteen persons in the banana-eating group who did get cancer, it would not be likely that any particular person in that cohort got it from the consumption of bananas. Correlation is not causation, and a substantial number of persons with cancer within the banana-eating group would in all probability have contracted the disease whether or not they ate bananas. FN6

The court's banana hypothetical is a clever and illustrative way of explaining an unfamiliar concept. It is a technique that could prove helpful in making a point to other members of the judiciary. Returning to the issue at hand, the Court went on to explain why Dr. Tikoo's was faulty:

> We think that this example exposes the analytical gap between Dr. Tikoo's methods and his conclusions. Although he could present figures ranging higher than50%, those figures were not responsive to the question of causation. Let us take the "stroke scale" figure from the National Institute on Neurological Disorders and Stroke (NINDS) study as an example. This scale measures the neurological deficits in different parts of the nervous system. Twenty percent of patients who experienced a stroke and were not treated with t-PA had a favorable outcome according to this scale, whereas that figure escalated to 31% when t-PA was administered.
>
> Although this means that the patients treated with t-PA had over a 50% better chance of recovery than they otherwise would have had, 69% of those patients experienced the adverse outcome (stroke-related injury) anyway.[FN7] The short of it is that while the odds ratio analysis shows that a t-PA patient may have a better chance of recovering than he otherwise would have had without t-PA, such an analysis does not show that a person has a better than even chance of avoiding injury if the drug is administered. The odds ratio, therefore, does not show that the failure to give t-PA was more likely than not a substantial factor in causing the plaintiff's injuries. The unavoidable conclusion from the studies deemed authoritative by Dr. Tikoo is that only a small number of patients overall (and only a small fraction of those who would otherwise have experienced stroke-related injuries) experience improvement when t-PA is administered.

Samaan and the cases cited by the First Circuit are hardly unique; the size of the risk ratio issue has helped the defense prevail in other t-PA malpractice cases around the country. *Joshi v. Providence Health System of Oregon Corp.*, 342 Or. 152, 156, 149 P. 3d 1164, 1166 (2006); *Ensink v. Mecosta County Gen. Hosp.*, 262 Mich.App. 518, 687 N.W.2d 143 (Mich.App. 2004) (affirming summary judgment for hospital and physicians when patient could not prove a greater than 50% probability of obtaining a better result had emergency physician administered t-PA within three hours of stroke symptoms).

Despite the above success in litigating dispositive motions in t-PA cases, the issue seems to go unnoticed in New York cases. For instance in *Gyani v. Great Neck Medical Group*, a stroke victim sued on various allegations of medical malpractice, including failure to administer t-PA. N.Y. S.Ct. for Nassau County, 2011 WL 1430037 (April 4, 2011). The trial court denied summary judgment on proximate cause grounds, and noted that

> "[t]he plaintiffs' expert ultimately opines that the failure to administer t-PA allowed Gyani's stroke to go untreated and progress to the point of her being locked-in permanently which would not have happened had t-PA been administered."

Id at *14. From the court's opinion, it appears defense counsel never pressed beyond the plaintiff's expert witness's conclusory opinion, devoid of quantified relative risk. Behind the curtain of that "ultimate" opinion is an expert without a meaningful basis for his opinion.

The *Samaan* decision provides defense counsel in New York with a blue print for challenging plaintiff's ability to prove proximate cause in a case based upon an allegation of a failure to timely administer t-PA to a patient suffering from an ischemic stroke. The NIH study is still the study upon which treatment with t-PA is based. Although there have been several recent articles concluding that the earlier t-PA is

given from onset to treatment, the better the result, the authors based their conclusions on the effectiveness of t-PA as established by the NIH study. Further, the conclusions about "ultra-early" administration of t-PA have no better odds ratios than the 1.5 seen in the NIH study. Therefore, these newer studies have the same inherent limitations in proving proximate and specific cause as the NIH study, and the same legal hurdles remain.

Although motion practice and hearings are costly, the odds of a pre-trial *Frye* challenge seem favorable for defense counsel to succeed. Success on these pre-trial motions would surely have a chilling effect on the plaintiffs' bar in commencing future actions. An added impetus to file these *Frye* challenges is to check the plaintiffs' bar's attempt to expand the number of lawsuits by using the ultra-early literature to argue that any delay even if within the three hour limitation, causes damages.

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OBSTETRICAL SIMULATION HOW FAR HAVE YOU COME?

By Joyce Lagnese, JD and Heather Marchegiani, BS

Obstetricians continue to experience some of the highest malpractice premiums among any specialty, largely due to the settlement and verdict values in malpractice cases. According to the Physician Insurer's Association of America's 2013 Edition of the "Risk Management Review", OB/GYNs rank second in the number of claims closed between 2003 and 2012, and first in the total indemnity paid between 2003 and 2012.

The American Congress of Obstetricians and Gynecologists (ACOG) has recently published several articles illustrating the severity of the malpractice situation. In September of 2012, ACOG released survey results that showed more than 50% of respondents had made changes to their practice as a result of the affordability or availability of liability insurance. In addition, 58% of respondents claimed to have made changes to their practice out of fear of being sued. Finally, over a three-year period between January 1, 2009 and December 31, 2011, 42% (over 9,000 respondents) of OB/GYNs reported being sued at least once. (https://www.acog.org/About_ACOG/News_Room/News_Releases/2012/Medical_Liability_Climate_Hurts_Patients_and_Ob-Gyns)

Unfortunately, New York State is not exempt from the "crisis". In March of 2012, ACOG released an "Analysis of the Current Medical Liability Climate in New York State," illustrating the impact the crisis is having on the care provided. According to ACOG, nearly 95% of all survey respondents indicated they had at least one claim filed against them during their career, with almost 50% indicating four or more claims. This report discussed the impact of medical malpractice premiums as well.

Physicians on Long Island can pay as much as $186,000 per year for liability insurance. Compare this to physicians in the Los Angeles market who pay on average $49,000, and physicians in Brownsville, Laredo, and El Paso, Texas who pay an average $62,000. Both the Los Angeles and Texas regions have experienced a decrease in the premiums between 2003 and 2010 (17% and 33%, respectively), while Long Island has seen almost a 51% increase over the same period of time. Finally, 93% of respondents indicated that they sometimes or often engage in defensive medicine to protect themselves against liability exposure. (http://mail.ny.acog.org/website/MedLiabilityRptFinal.pdf)

To address these concerns, many hospitals and physicians are implementing structured curriculums to educate their providers on strategies to mitigate risk in high exposure areas. These efforts could have a significant impact on claims and liability insurance according to an article published in December of 2008 in Obstetrics and Gynecology. The study indicated that payment in 85% of cases involving fetal monitoring (non-VBAC), 90% of cases involving VBAC,

and 54% of shoulder dystocia cases could have been avoided had specific practice and documentation patterns been adhered to. (https://ps.mcic.com/appdocs/lps/reducing%20ob%20litigation%20through%20alterations%20in%20practice%20patterns.pdf)

Recently, simulation training has been deployed across many specialties to provide clinicians with an opportunity to perfect their skills in a particular area or procedure. A study published in the National Institute of Health in August 2011 indicated that simulation-based medical education can assist with long-term retention of clinical skills, and can improve patient care practices and public health (http://www.ncbi.nlm.nih.gov/pubmed/21705966). As obstetricians continue to face skyrocketing medical malpractice premiums, settlement values, and jury verdicts, perhaps simulation could provide the much needed solution to improving the medical malpractice climate for obstetricians while simultaneously improving patient care.

When examining the exact impact of simulation on patient care, it became clear that some specialties have done their own research and studies on educating providers on high-risk issues through simulation. For example, the Departments of Anesthesia at the University of Rome La Sapienza and The Ohio State University Wexner Medical Center together analyzed the impact of simulation on weaning patients from cardiopulmonary bypass. The study examined a control group who participated in the traditional seminar-based education versus a group who participated in simulation-based education on the same topic. Those who learned through simulation scored an 89.9% on the post-test, while the seminar-based group only averaged a 75.4%. It was also determined that retention of the material five weeks post-education was significantly higher for the simulation group. While this data is promising, the article noted there is little research and evidence available as to whether this corresponds with improvements in clinical competence and/or patient care. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3842047/)

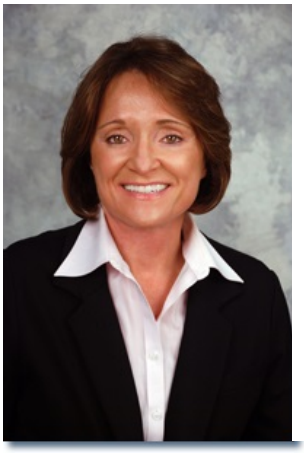
One common concern raised by physicians regarding simulation is the cost associated with the training. However, not all training is expensive. In an article published in the Royal Australian and New Zealand College of Obstetricians and Gynaecologists Journal, a literature search resulted in confirmation that there can be an increase in knowledge and skills as a result of simulation training, even if cost is a barrier and high-tech equipment is unavailable (http://onlinelibrary.wiley.com/doi/10.1111/ajo.12120/abstract). By designing education programs that highlight processes and communication strategies, errors related to unfamiliarity with postpartum hemorrhage protocols or shoulder dystocia could be avoided. For example, requiring participants to walk through the current postpartum hemorrhage protocol "in situ", rather than a simulation lab, could remind both physicians and nurses of the necessary processes that must be followed to maximize safety and improve patient outcomes.

However, particularly in obstetrics, few studies have been done to link the impact of simulation to patient care. This could take several years to measure. Potential methods of measuring this impact could be through patient satisfaction scores, claims trends, and anecdotal feedback from physicians. If this correlation does exist, it could result in lower malpractice premiums as the claims start to decline and the cost of insuring obstetricians decreases.

New York is at an ideal time to engage in these simulation research opportunities. With premiums nearing $200,000 in some areas, obstetricians are going to be forced to modify their practice or leave the practice of medicine altogether. In fact, between 1995 and 2003, 14 hospitals in New York terminated their obstetrical services. Some patients are now forced to travel over an hour to seek care. And, many providers are refusing to treat high risk patients. Of 187 OB/GYNs included in a survey, 59% reported that they often refer high-risk patients to other providers in unnecessary circumstances to avoid liability exposure. This, in turn, is creating more risk and potential harm for patients, as well as the providers who do, in fact, accept responsibility for this care. (http://mail.ny.acog.org/website/MedLiabilityRptFinal.pdf)

In summary, New York is, in fact, experiencing a medical malpractice crisis and unfortunately the field of obstetrics is not exempt. While it is not the end-all, be-all, engaging in simulation programs and education could assist hospitals and physicians in proactively mitigating risk and enhancing patient care. If done effectively, the simulation programs and education could also positively impact malpractice premiums. The ensuing improved patient care, decreased risk for providers, and declining malpractice premiums could help New York obstetricians as a whole provide a better, more satisfying patient experience. Assuming the aforementioned benefits are true, this is an environment worth simulating any day.

About the Authors



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WARNING: EVERYONE PLAYS A ROLE IN AVOIDING CYBER LIABILITY

By Betsy D. Baydala, Esq.

The headlines are becoming all too common – "*Forty Million Target Customers Affected by Data Breach*,"[1] "*Neiman Marcus Sued Over Customer Credit Card Data Breach*,"[2] "*Heartbleed Bug Exposes Passwords, Web Site Encryption Keys*."[3] The risk is real, "Big Data" exists, and everyone's privacy and security are becoming harder to protect. Major industries, such as finance, education, hospitality, and retail, are under increased scrutiny and subject to compliance with a proliferation of federal, state and local laws intended to protect personal information.

The health care sector is no exception. In fact, the Federal Bureau of Investigation's ("FBI") Cyber Division recently issued a notification to the health care sector warning that health care systems and medical devices are at risk for increased cyber intrusions for financial gain.[4] The FBI predicts increased cyber intrusions due to the "mandatory transition from paper to electronic health records, lax cybersecurity standards, and a higher financial payout for medical records in the black market." In addition, the FBI cautions that with more medical devices being connected to the internet "a rich new environment for cyber criminals" is being generated.

HIPAA

Due in large part to these continually evolving risks, the U.S. Department of Health and Human Services ("HHS") has revamped its national standards for the protection of patient health information. HHS' foremost regulations in this area are the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Clinical and Economic Health Act ("HITECH"). The major components of HIPAA, and as amended by HITECH, are the Privacy, Security, Breach Notification and Enforcement Rules intended to enhance patient privacy and security protections, provide individuals with certain rights and control over their health information, and strengthen the government's ability to enforce the law.

HIPAA applies to "covered entities," which is defined as a health plan, a health care clearing house, or a health care provider who transmits any health information in electronic form in connection with a transaction covered under HIPAA.[5] Given the government's nationwide efforts for health care providers to implement and use the most advanced health information technology and to adopt electronic medical records, nearly every health care provider is considered a "covered entity" and subject to HIPAA's requirements.

HIPAA is a highly complex, nuanced federal statute. Although compliance may feel like a daunting task for most health care providers, it is a realistic outcome with sufficient time, attention and consultation with legal counsel. The following is a general summary of each of the four major HIPAA rules.

1) Privacy Rule

The HIPAA Privacy Rule establishes national standards for covered entities to safeguard the privacy of individually identifiable health information (or personal health information ("PHI")).[6] This rule sets limits and conditions on the use and disclosure of PHI without patient authorization. It also gives patients' rights over their health information, such as the right to examine and obtain a copy of their health records and request corrections. The HIPAA Privacy Rule is balanced in that it provides for the protection of PHI held by a covered entity, while permitting the disclosure of health information as needed for patient care and other important purposes. If a covered entity becomes aware of an improper disclosure of PHI, the HIPAA Privacy Rule requires the covered entity to mitigate, to the extent practicable, any harmful effect caused by such disclosure.

1) Security Rule

The HIPAA Security Rule sets forth a series of administrative, physical and technical safeguards for covered entities to ensure the confidentiality, integrity, and availability of individuals' electronic personal health information ("ePHI").[7] For example, a covered entity must identify and protect against reasonably anticipated threats to the security or integrity of ePHI. Protecting ePHI's "integrity" means preventing the alteration or destruction of ePHI in an unauthorized manner. A covered entity must also protect against reasonably anticipated, impermissible uses or disclosures of ePHI, and ensure compliance by its workforce.

The HIPAA Security Rule is flexible and allows a covered entity to analyze its own needs and implement safeguards appropriate for its own environment. When deciding on which security measures to implement, a covered entity must consider its size, complexity and capabilities; its technical hardware and software infrastructure; the costs of security measures; and the likelihood and possible impact of potential risks to ePHI. Because of the rapidly changing technological environment, the HIPAA Security Rule requires covered entities to periodically review and, as appropriate, modify their security measures.

3) Breach Notification Rule

The HIPAA Breach Notification Rule requires covered entities to provide notification following a breach of unsecured PHI.[8] Generally, a breach is defined as an impermissible use or disclosure of PHI that compromises the security or privacy of the PHI by posing a significant risk of financial, reputational, or other harm to the individual.[9] An impermissible use or disclosure of PHI is presumed to be

a breach, unless after the performance of a risk assessment of a number of factors enumerated under HIPAA the covered entity demonstrates that there is a low probability that the PHI was compromised.

4) Enforcement Rule

The HIPAA Enforcement Rule contains provisions relating to compliance and investigations, as well as the imposition of civil monetary penalties for violations of HIPAA.[10] HHS' Office of Civil Rights ("OCR") is responsible for enforcing the HIPAA Privacy and Security Rules (since 2003 and 2007, respectively). OCR's main functions are the investigation of HIPAA complaints filed with OCR (12,915 complaints were filed in 2013)[11]; compliance reviews to determine if covered entities are in compliance with HIPAA; and performance of education and outreach to foster compliance with the HIPAA Privacy and Security Rules.

If OCR determines after an investigation or compliance review that a covered entity has not complied with HIPAA, OCR will attempt to resolve the case through voluntary compliance, corrective action and/or a resolution agreement with the covered entity. A resolution agreement is a binding contract signed by HHS and the covered entity, whereby the covered entity agrees to perform certain obligations (e.g., staff training) and likely agrees to the payment of a resolution amount. A resolution agreement is typically used to settle more serious violations of HIPAA. If the covered entity does not take satisfactory action to resolve the matter, OCR may decide to impose civil monetary penalties ("CMPs"). To date, HHS has entered into 21 resolution agreements and issued CMPs to one covered entity.

State Attorney Generals also have the authority to bring civil actions against a covered entity on behalf of state residents for violations of the HIPAA Privacy and Security Rules.[12] State Attorney Generals are permitted to obtain damages on behalf of state residents or to enjoin further violations of HIPAA.

Recent Examples and Consequences of HIPAA Non-Compliance

Because HIPAA compliance is mandatory, a covered entity faces serious financial and reputational consequences due to non-compliance. In recent years, OCR has taken a more active role in its enforcement powers and entered into record breaking resolution agreements to resolve actual and suspected violations of HIPAA.

In OCR's latest HIPAA settlement, New York and Presbyterian Hospital ("NYP") agreed to pay $3.3 million and adopt a corrective action plan to settle potential violations of the HIPAA Privacy and Security Rules.[13] According to the resolution agreement, on September 27, 2010, NYP notified OCR of a breach of its unsecured ePHI after NYP received a complaint from an individual who found a deceased partner's patient information on the internet. It was ultimately determined that this breach incident stemmed from the impermissible disclosure of ePHI of 6,800 patients to internet search engines, such as Google, when a computer server that had access to NYP ePHI information systems was errantly reconfigured. After HHS' investigation, it determined that before the breach incident NYP had failed, in part, to implement sufficient security measures and monitoring systems to reduce the risks and vulnerabilities to its ePHI.

Pursuant to the resolution agreement with HHS, NYP agreed to take the following corrective actions: (1) conduct a comprehensive and thorough risk analysis of security risks and vulnerabilities; (2) develop and implement an organization-wide risk management plan to address and mitigate any security risks and vulnerabilities found in its risk analysis; (3) review and revise its internal policies and procedures for authorizing access to NYP ePHI; (4) develop a process to evaluate any environmental or operational changes that affect the security of NYP ePHI; (5) review and revise its policies and procedures related to the use of hardware and electronic media, including but not limited to laptops, tablets, mobile phones, and USB drives, that may be used to store, download, or transmit NYP ePHI; and (6) augment its existing Health Information Privacy and Security Awareness Training Program.

As a result of the NYP breach incident, Columbia University ("Columbia") also entered into a resolution agreement with HHS and agreed to pay $1.5 million because NYP and Columbia operated a shared data network linked to the NYP's information system. After its investigation, HHS determined that Columbia had failed to conduct a thorough risk analysis and failed to implement sufficient security measures of its server accessing NYP-ePHI.

The NYP breach incident totaled a record breaking $4.8 million in HIPAA settlement costs alone. However, the full economic impact on NYP and Columbia was much larger after accounting for forensics, notification, legal, and public relations costs. According to a recent study from Ponemon Institute ("Ponemon Study"), data breaches cost health care organizations millions of dollars every year, costing the health care industry as a whole an estimated $5.6 billion annually.[14]

1) The Risk of "Theft/Loss"

In Verizon's 2014 Data Breach Investigations Report ("Verizon's Report"), security incidents across all industries were studied in an effort to identify "incident classification patterns" and discern the differing threat profiles across each industry. According to Verizon's Report, 46% of all Health Care industry security incidents are due to "theft/loss." In comparison, only 3% of Finance industry security incidents are caused by "theft/loss."

Consequently, Verizon identified "theft/loss" in the Health Care industry as a "hot spot," meaning "theft/loss" is a major threat to the security of health care data. Remarkably, the Health Care industry was the only industry out of 19 with "theft/loss" being identified as a "hot spot" threat. A possible explanation for this finding is consistent with the FBI's notification that there is a "high financial payout for medical records in the black market." PHI is unique in that it contains multiple classes of information to exploit thus making it extremely valuable data.

Not surprisingly, HHS has entered into a number of resolution agreements with health care providers due to the theft of unencrypted laptops containing ePHI. In December 2011, Concentra Health Services ("Concentra") notified HHS of a breach of its unsecured ePHI after an unencrypted laptop was stolen from its physical therapy center. As a result of this breach incident, in April 2014, Concentra agreed to pay HHS over $1.7 million and implement a number of corrective actions. As part of its corrective action obligations, Concentra must update HHS with the following information regarding its encryption status: (1) the percentage of all devices and equipment (laptops, desktops, medical equipment, tablets, and other storage devices) that are encrypted; (2) evidence that all new devices and equipment have been encrypted; (3) an explanation for the percentage of devices and equipment that are not encrypted; and (4) a breakdown of the percentage of encrypted devices and equipment for each specific Concentra facility and worksite.

Given the significant threat of "theft/loss" of medical records, it is critical for HIPAA covered entities to encrypt all ePHI as specified in the HIPAA Security Rule. Encryption of "data in motion" is vital as many health care providers permit employees and medical staff to use their own mobile devices, such as smart phones and tablets, to connect to their organization's networks or enterprise systems. HIPAA defines "encryption" as "the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key."[15] Valid encryption processes must generally comply with the National Institute of Standards and Technology ("NIST") standards rendering PHI "unusable, unreadable, or indecipherable to unauthorized individuals."

2) The Risk of "Insider Misuse"

According to Verizon's Report, after "theft/loss," "insider misuse" is the next highest security incident classification pattern in the Health Care industry at 15%. While 15% is not a large percentage, it is a significant percentage when considered as the next biggest security threat to the Health Care industry. In apparent awareness of the threat of "insider misuse," 75% of the organizations polled in the Ponemon Study reported employee negligence as their biggest worry when it comes to security. In addition, Kroll's 2014 Cyber Security Forecast predicts "a significant number – if not almost half – of data breaches will come at the hands of people on the inside."[16]

Accordingly, not only is employee training mandatory under HIPAA, it can serve as an effective measure in reducing the "insider misuse" of PHI and ePHI in the health care industry. In addition, sufficient security safeguards must be implemented so that only those persons with authority to use PHI can access the information. Moreover, a procedure must be in place whereby any employee or staff can immediately repot unauthorized access, use or disclosure of PHI/ePHI.

Conclusion

In today's hyper digital world, nearly every health care provider is a "covered entity" and subject to compliance with HIPAA. As a health care provider creating, maintaining and transmitting ePHI, there is a mandatory expectation that all IT equipment, applications and data systems utilizing ePHI are reasonably secure, and that all employees and staff are adequately trained. A recent report from SANS Institute ominously warns that IT professionals working for health care related industries believe their network perimeter defenses are their most effective security and compliance measures, despite data showing those devices (e.g., radiology imaging software, faxes) and applications (e.g., firewalls, routers) are increasingly being breached and emitting malicious traffic.[17]

Given this disconnect between perception and reality, it is time for health care providers to have an open and honest dialogue about the privacy and security of PHI/ePHI. This requires collaboration throughout the entire health care organization, from executives to the IT department and staff, with the ultimate goal of improving health care.

Article References Listed on page 25

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REGULATORY UPDATE

UNDERSTANDING AMBULATORY SURGERY CENTERS

By Mathew J. Levy, Esq., Stacey Lipitz Marder, Esq.

Introduction:

It is no secret that ambulatory surgery centers ("ASCs") are becoming the go to place for physicians to perform procedures as opposed to hospitals as physicians attempt to increase revenue and align with hospitals. As per the Centers for Medicare and Medicaid Services (CMS), an ASC is defined as followed: "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. See 42 cfr § 416.2 Definitions. While there are certainly several benefits to ownership in an ASC, prior to jumping on the ASC bandwagon, it is imperative that physicians and other investors understand the process of starting/operating an ASC, as well as evaluate the legal, business and regulatory implications. Although the corporate practice of medicine doctrine in New York State generally prohibits general business corporations from employing physicians for the purpose of providing medical services or arranging for the provision of medical services, ASCs, unlike medical practices, can be owned by non-physicians. See NY BCL §1501 et seq.; NY Education Law §6522

CON Process:

In order to operate an ASC in New York, approval must be obtained from the Department of Health and Health Planning Committee via the Certificate of Need (CON) process. The objectives of the CON process are to promote delivery of high quality health care and ensure that services are aligned with community need. The CON process can be very involved and can often take several months to complete. All proposed operating documents have to be submitted, in addition to floor plans and other information pertaining to the project.

In order to increase the probability that approval is granted, many ASCs are partnering with hospitals as hospitals often are able help prove the need for an ASC in the community. Additionally, hospitals have an interest in entering into joint ventures with ASCs as it is more cost effective to perform procedures at an ASC as opposed to a hospital.

Legal Documents:

Prior to commencement of the CON application process, proposed documents in connection with the ASC need to be drafted. For instance, formation documents (Articles of Organization/Certificate of Incorporation) need to be drafted, as well as operating documents (operating agreement/shareholders agreement) dictating the terms regarding how the ASC will be governed and the rights of its owners. There are several key provisions to consider in such operating documents. For instance, potential investors should ascertain information regarding how distributions are made, how decisions are made with respect to the ASC, as well as who is responsible for the day to day management and decision making. Furthermore, potential investors should consider how new members are added, as well as what their buy-in will be. Termination provisions are also important to consider, specifically how an owner can be terminated (without cause or with cause), whether an owner has an exit strategy in the event the owner wants to terminate the relationship, as well as what the buy-out terms are in the event of termination. Furthermore, it is important to consider whether there is a restrictive covenant and non-solicitation provision, which may preclude the physician investor from having an ownership interest in another ASC within a certain geographic region, as well as soliciting patients, employees and referral sources. A Subscription Booklet, including a Subscription Agreement, should also be drafted and distributed to potential investors. Such documents would outline the terms of the venture, including but not limited to investment terms, and the proposed terms of a lease agreement, billing agreement, consulting agreement, and escrow agreement, as applicable. A questionnaire should also be distributed to obtain information regarding potential investors for due diligence purposes.

Regulatory Concerns:

In the event an investment is made by a physician and there are referrals being made, the federal and state rules and regulations governing referrals must be reviewed, including but not limited to the Stark Law and Anti-kickback Statute.

While the Stark Law (self-referral statute) has significantly restricted the possibility of many physician joint ventures, it does not prohibit a physician from entering into an arrangement with an ASC. The Stark law prohibits physicians from referring Medicare patients to an entity for certain "designated health services" if the physician has a financial relationship with that entity, subject to certain exceptions. Since ASC services are not, themselves, "designated health services" covered by the Stark law, the Stark Law does not restrict physician ownership of ASCs, so long as the ASC does not provide any separately billable designated health care services. See 42 USC § 1395NN

However, an investment by a physician in an ASC can implicate the Anti-kickback Statute. The Ant-kickback Statute prohibits any person from "knowingly and willfully" providing any remuneration to induce referrals, or in exchange for referrals, of federal health care program patients or business. See 42 U.S.C. § 1320a-7b(b) Accordingly, the

Anti-kickback Statute applies to any physician-owned ASC that treats federal health care program patients (including Medicare and Medicaid) since the physician's return on investment can arguably be viewed as an inducement for physician investors to refer patients to the ASC.

Such arrangement would not run afoul of the Anti-kickback Statute in the event the arrangement falls within the parameters of an applicable safe harbor, specifically those which protects various types of physician-owned ASCs as well as hospital/physician ASC joint ventures. See 42 C.F.R. § 1001.952(r) Although safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor, the absence of safe harbor protection is not fatal, rather the arrangement may be subject to further scrutiny.

The ASC safe harbor generally excepts from the definition of "remuneration" payment that is a return on an investment interest made to an investor, so long as the investment entity is a Medicare-certified ASC, the ASC's operating and recovery room space is dedicated exclusively to the ASC, patients referred to the ASC by an investor are informed fully of the investor's investment interest, and all of the applicable standards are met within one of four categories: surgeon-owned ASCs, single-specialty ASCs, multi-specialty ASCs and hospital-physician ASCs.

Some standards which are applicable to each of the categories are as follows: See 42 C.F.R. § 1001.952(r)

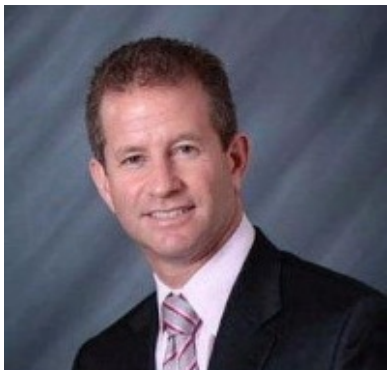
- the terms on which an investment interest is offered to an investor must not be related to services furnished, the previous or expected volume of referrals or the amount of business otherwise generated from that investor to the entity;
- any distribution or dividend payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair-market value of any pre-operational services rendered) of the investor;
- at least one-third of each surgeon investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of those procedures on the list of Medicare-covered procedures for ASCs (with respect to a multi-specialty ASC, at least one-third of these procedures must be performed in the ASC as well);
- any and all ancillary services for federal health care program beneficiaries performed at the ASC must be directly and integrally related to primary procedures performed at the ASC, and none may be separately billed to any federal health care programs, including Medicare; and
- the ASC and any surgeon investors must treat federal health care program beneficiaries in a non-discriminatory manner

It is important to note that physicians must also disclose in writing their ownership interest in an ASC to patients. See 42 CFR Part 420 ASCs must also ensure that all rules and regulations governing patient confidentiality, including but not limited to HIPAA, are complied with, and that all billing and coding rendered in connection with services rendered at the ASC are accurate and are substantiated by the medical records.

Conclusion:

In sum, investing in an ASC can be a great opportunity for physicians and other non-physician investors. To that end, prior to participating, it is in the best interest of potential investors to evaluate the opportunity from a business, as well as regulatory perspective in order to ensure maximum benefit.

About the Authors



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THE MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT OF 2008 FINAL RULE HIGHLIGHTS

By Ruth Nayko, RN MBA CPHQ CPPS CPHRM

The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) is a federal law that overall was designed to prevent group health plans and health insurance issuers that provide mental health or substance use disorder (MH/SUD) benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical benefits. MHPAEA initially applied to group health plans and group health insurance coverage and was amended by the Affordable Care Act in 2010 to also apply to individual health insurance coverage. The Department of Health and Human Services (HHS) has jurisdiction over non-federal governmental plans and the Departments of Labor (DOL) and the Treasury have jurisdiction over private group health plans. A final regulation implementing MHPAEA was published in the Federal Register on November 13, 2013. The regulation became effective January 13, 2014 and generally applies to plan years beginning on July 1, 2014. In practice, the majority of plan years end December 31 so the effective date for most insured will be January 1, 2015. This followed an interim final regulation which had been published in the Federal Register on February 2, 2010 and applies to plan years beginning on July 1, 2010.[1] The complete 206-page final rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-27086.pdf.

Overall, the final regulation clarifies many issues that had been vague in the interim regulations. The American Psychiatric Association (APA) issued a news release stating that "People with mental illness have long faced discrimination in health care through unjust and often illegal barriers to care. … The final rule provides a crucial step forward to ensure that patients receive benefits they deserve and are entitled to under the law." [2] The APA reviewed the final rule and provided a brief summary of key provisions for its members. [3] A brief summary of the final rule key provisions is provided below.

General Parity Requirement

The final rule describes the general parity requirement as a group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits. This group health plan may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification.

Scope of Service

The final rule clarifies the scope of service. There are six classifications of benefits:

- inpatient in-network;
- inpatient out-of-network;
- outpatient in-network;
- outpatient out-of-network;
- emergency and
- prescription drug.

Sub-classifications are permitted for office visits separate from all other outpatient services, as well as for plans that use multiple tiers of in-network providers. Although the regulation does not require plans to cover MH/SUD benefits, if they do, they must provide MH/SUD benefits in all classifications in which medical/surgical benefits are provided. The substantially all/predominant test outlined in the statute must be applied separately to each of the six classifications of benefits.[4] The final rule describes the "substantially all" requirement that if a type of financial requirement (deductibles, copayments, coinsurance, and out-of-pocket maximums) or quantitative treatment limitation (annual, episode, lifetime day and visit limits) does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance used disorder benefits in that classification. If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical-surgical benefits in that classification subject to the financial requirement or quantitative limit. Several examples are provided in the final rule. Example 3 on page 116 of the rule states:

> "Facts. A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations. Conclusion. In this Example 3, because the plan has no network of providers, all

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because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/ surgical benefits. Because the co-insurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/ surgical benefits is determined without regard to coverage units."

Plans and issuers must assign mental health and substance use disorder benefits and medical/surgical benefits to the six classifications in a consistent manner. This general rule also applies to intermediate services provided under the plan or coverage such as intensive outpatient, partial hospitalization and residential.[5] Plans and issuers must assign covered intermediate mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications. An example provided on page 27 of the final rule states, "if a plan or issuer classifies care in skilled nursing facilities or rehabilitation hospitals as inpatient benefits, then the plan or issuer must likewise treat any covered care in residential treatment facilities for mental health or substance user disorders as an inpatient benefit. In addition, if a plan or issuer treats home health care as an outpatient benefit, then any covered intensive outpatient mental health or substance use disorder services and partial hospitalization must be considered outpatient benefits as well."

Non-Quantitative Treatment Limitations (NQTL)[6]

- Non-quantitative treatment limitations include for example, medical management and pre-authorization. There is an illustrative list of non-quantitative limitations in the regulation.
- The final rule eliminated the provision included in the interim final rule that permitted plans to apply subjective limits on MH/SUD treatment if there was a "clinically recognized standard of care that permitted a difference."
- In the final rule, parity requirements for NQTLs are expanded to include restrictions on geographic location, facility type, provider specialty and other criteria that limit the scope or duration of benefits for services. This includes access to intermediate levels of care. Thus, plans that allow members to go out of state for medical/surgical services will be required to allow a patient to go to an MH/SUD facility out of state.
- The final rule continues the "comparable and no more stringently" standard on NQTLs and maintains the requirement that plans disclose the "processes, strategies, evidentiary standards and other factors used by the plan or issuer to determine whether and to what extent a benefit that is subject to an NQTL be comparable and applied no more stringently for MH/SUD than for medical/surgical."
- An improvement in the final rule is that plan participants or those acting on their behalf are now able to request a copy of all relevant documents used by the health plan to determine whether a claim is paid. Further information is provided below under Disclosure.
- The final rule affirms that provider reimbursement rates are a form of NQTL. Plans and issuers may consider a wide array of factors in determining provider reimbursement rates for both medical/surgical services and MH/SUD, such as service type; geographic market; demand for services; supply of providers; practice size; Medicare reimbursement rates; and training, experience and licensure of providers. The NQTL provisions require that these or other factors be applied comparably to and no more stringently than those applied with respect to medical/surgical services.[7]

Disclosure

The FAQS About Affordable Care Act Implementation (Part XVII) And Mental Health Parity Implementation published jointly by HHS, the DOL and Treasury explain that MHPAEA provides that the criteria for medical necessity determinations with respect to MH/SUD benefits must be made available to any current or potential participant, beneficiary, or contracting provider upon request. In addition, the reason for denial of reimbursement or payment for services with respect to MH/SUD benefits must be made available to participants and beneficiaries.

Also, under the internal appeals and external review requirements added by the Affordable Care Act, group health plans must provide to an individual upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the individual's claim for benefits consistent with the DOL's claims procedure regulation. The plan or issuer must also provide the claimant with any new or additional evidence considered, relied upon, or generated by the plan or issuer must provide the claimant win any new or additional evidence considered or generated by the plan or issuer in connection with a claim. If an adverse benefit determination is being issued on review based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale.[8]

Additionally, under the final rule, documents with information on medical necessity criteria for both medical/surgical and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a non-quantitative treatment limitation, are instruments under which the plan is operated, must be provided to a participant within 30 days of request.[9]

State Preemption

Some states may have mental health parity requirements that are stricter than federal requirements. To view State specific information visit www.ncsl.org.[10]

Tiered Networks

The final rule allows plans and issuers to use multiple provider network tiers but they cannot impose these tiered networks more stringently on MH/SUD subject to the general test provided for NQTLs.[11]

Multi-Tiered Prescription Drugs

A plan may have multi-tiered prescription drug programs. A plan cannot apply these tiered prescription drug programs more stringently ton MH/SUD prescription drugs.[12]

Exemptions

The final rule provides a formula for how plans and issuers can file a cost exemption if the changes required to comply with the law raise costs by at least 2% in the first year. Also, local and state self-funded plans may continue to apply to CMS for an exemption from MHPAEA's requirements.[13]

Conclusion

Historically, insurers have provided different coverage for the treatment of mental health or substance use disorders than for treatment of medical/surgical conditions -often considerably less. The final rule governing the implementation of the MHPAEA initiates bringing mental health or substance use disorder and medical/surgical coverage into equilibrium.

Article References Listed on page 25

The Hazards of Pharmaceutical Disposal: An Arising Risk in Healthcare **.....from page 3**

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[3] 40 C.F.R. § 302.4; 6 NYCRR Part 597.2.

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[5] See 33 U.S.C.A. §§ 1251 to 1387.

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[7] *See* US. Dep't of Envtl. Prot., Unused Pharmaceuticals in the Health Care Industry: Interim Report, August 2008, *available at* http://water.epa.gov/scitech/swguidance/ppcp/upload/2010_1_11_ppcp_hcioutreach.pdf.

[8] *See* U.S. Dep't of Envtl. Prot., Management of Hazardous Waste Pharmaceuticals, *available at* http://www.epa.gov/waste/hazard/generation/pharmaceuticals.htm.

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[14] *See* Management of Hazardous Waste Pharmaceuticals, *supra* n. 2.

[15] *Id.*

[16] *See* Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States, *supra* n. 4.

[17] Illinois, for example, created the Safe Pharmaceutical Disposal Act., which prohibits health care institutions and their staff from flushing unused medications into public wastewater collection systems or septic systems. Illinois has also implemented a $500 penalty for the violation of this prohibition. *See* 210 Ill. Comp. Stat. 150/10.

[18] This EPA report is available at http://water.epa.gov/scitech/wastetech/guide/upload/unuseddraft.pdf.

[19] *Id.*

[20] *See* Secure and Responsible Drug Disposal Act of 2010, Pub. L. 111–273, 2 (Oct. 12, 2010) 124 Stat. 2858

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *See generally* Fed. Reg., Dec. 21, 2012, Vol. 77, No. 246.

[25] *Id.* In the regulations, the DEA proposes to delete 21 C.F.R. § 1307.12 on "distribution to supplier or manufacturer" and 21 CFR § 1307.21 on "disposal of controlled substances" and "promulgate a new part 1317 that will expand available disposal options, establish nationwide standards for the disposal of controlled substances, and comprehensively outline the process and procedure for the disposal of controlled substances by registrants, ultimate users, and other non-registrants such as long term care facilities." *Id.* at 75789.

[26] *See* Press Release: The New York State Attorney General Andrew M. Cuomo Announces Groundbreaking Settlements To Stop 5 Healthcare Facilities From Disposing Of Pharmaceutical Wastes Into The NYC Watershed (Jan. 12, 2010), *available at* http://www.ag.ny.gov/press-release/new-york-state-attorney-general-andrew-m-cuomo-announces-groundbreaking-settlements. The Press Release includes links to each respective health care facility's assurance of discontinuance.

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In an effort to educate the public about the environmental concerns created by flushing pharmaceuticals, the NYSDEC has launched a campaign website at http://www.dontflushyourdrugs.net.

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[32] *See* Household Drug Collection Schedule, *available at* http://www.dec.ny.gov/chemical/63826.html, for a list of the precincts and local organizations in Long Island and other areas of New York where individuals can dispose of household pharmaceuticals.

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[2] http://www.bloomberg.com/news/2014-03-12/neiman-marcus-sued-over-customer-credit-card-data-breach.html

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