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Nurse practitioners and physician assistants: Managing potential liability in the physician office

BY ANN D. GAFFEY, RN, MSN, CPHRM, DFASHRM

Without the use of nurse practitioners and physician assistants to support physicians in providing care in the office setting, it would be even more difficult to care for the volume of people seeking healthcare in the United States today. Nurse practitioners (NP) and physician assistants (PA) practice in all 50 states and Washington, D.C., improving access to care, quality of care and patient satisfaction across the country. In the most recent data reported by the Henry J. Kaiser Family Foundation, there were 180,233 nurse practitioners¹ and 83,466 licensed physician assistants in the United States.² Compare that to 834,769 total professionally active physicians³, and we have almost 1.1 million providers, a quarter of which are either independently practicing or working in a supervised capacity in a team to help physicians deliver much-needed care.

Where the confusion may lie is in how each of these providers may practice based on how they are regulated in different states. Both professions have prescriptive rights in all 50 states, with some limitations varying from state to state. While some states have no requirements for an NP to have a collaborative relationship with a physician or other provider, making NPs more "independent," other states do have requirements for a collaborative agreement to be in place. For PAs, as noted by the American Association of Physician Assistants, "Some state PA practice laws and regulations use the word 'protocol' to describe the practice arrangement between a physician and a PA, while other states direct physician-PA teams to use detailed clinical protocols to define a PA's practice. These differing uses for the term 'protocol' create confusion for PAs and those who hire them."⁴

Often referred to as "mid-level providers" or "physician extenders," the professional organizations supporting these two groups feel differently. The American Association of Nurse Practitioners (AANP) opposes use of

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When designing a risk mitigation plan as part of employing and supervising NPs and PAs to support patient care in the office practice setting, consider the following:

1. Verify that adequate liability coverage for NPs and PAs will be provided by the supervising physician's professional liability carrier.
2. Have a clear understanding of state law regarding scope of practice for NPs and PAs in the state or states the practice has offices, including but not limited to the number of providers a physician may supervise, limits on sequential visits a patient may have with an NP or PA for ongoing problems, and where the supervising physician may geographically reside when an NP or PA is seeing patients. Seek legal counsel for clarification if necessary.
3. Conduct the appropriate due diligence during the hiring process to confirm training, certification and licensure of the individual. This important step can minimize the risk of litigation around negligent selection and even criminal charges, should a person hired be unlicensed.
4. Develop written supervisory agreements, protocols, etc. as directed by state law and regulation. Ensure a copy of the agreement is available in the office, on file with the appropriate Board as directed, and made available to the Board upon request.
5. Verify that each NP or PA has a clear understanding of their obligations as part of the team, including scope of practice, limits on sequential visits with patients with ongoing acute problems and methods and frequency of communication with supervising physicians. Expect and encourage ongoing communication with the supervising physician.
6. Ensure the supervising physician only co-signs progress notes that have been reviewed and that the plan of care is agreed upon.
7. Ensure each provider is appropriately identified by name and title to each patient, through use of clearly visible name tags and personal introduction to each patient seen.
8. Establish regular meeting times to review complex patients, share information, clarify treatment plans and maintain ongoing communication channels.
9. Ensure the administrative staff members scheduling patient visits are aware of any limits on repetitive visits by an NP or PA, in an effort to reduce the likelihood that a patient could be seen more times in a row by an NP or PA than is allowed, based on state law.
10. Ensure the supervising physician conducts periodic performance review and random chart reviews with the NP or PA and that these activities are documented.
11. Be diligent in scheduling annual reviews of any written agreement or protocol with the NP and PA in the office setting, recognizing that these care teams evolve in the way they deliver care. As skills and confidence between team members grow, the scope of practice may extend in clinical practice, but not be reflected in the written agreements that memorialize what the physician has agreed to.

terms such as “mid-level provider” and “physician extender” in reference to nurse practitioners individually or to an aggregate inclusive of NPs. Their position is that, “NPs are licensed, independent practitioners. AANP encourages employers, policy-makers, healthcare professionals and other parties to refer to NPs by their title. When referring to groups that include NPs, examples of appropriate terms include: independently licensed providers, primary care providers, healthcare professionals and clinicians.”⁵ Similarly, the American Academy of Physician Assistants believes that, whenever possible, PAs should be referred to as “physician assistants” and not combined with other providers in inclusive non-specific terms such as “midlevel practitioner,” “advanced practice clinician” or “advanced practice provider.”⁶

Putting specific state laws and regulations aside, at the end of the day the supervising physician of either an NP or PA is ultimately responsible for the care provided in their name, and retains the professional and legal responsibility for care rendered by both an NP and PA. In legal terms, several theories of liability are relevant, and in cases stemming from the office

practice setting they may include direct liability and vicarious liability allegations. Because in most physician practices the NP or PA is employed by the group, the doctrine of respondeat superior is likely to apply. In these instances where there is an employer-employee relationship, the principle applies that the employer or “master” must answer and be responsible for the acts and omissions of the employee performed within his or her employment. As noted by Saxton and Finkelstein, “when appropriate supervising and collaborative measures are not in place, or are not followed, patient care can be negatively impacted and physician liability exposure can increase. Rarely are lawsuits filed solely against a mid-level; but rather, lawsuits involving care by a mid-level focus on the supervising physician as well.”⁷

When professional liability claims are made, frequently seen allegations include failure or delay in diagnosis due to inadequate physician supervision, inadequate examination, delayed referral to a supervising physician, failure to have a collaborative agreement in place, failure to follow the requirements of the collaborative agreement and the NP or PA

practicing outside the scope of their agreement.^{8,9,10} Drilling into professional liability claims experience for NPs, four locations accounted for a significant percentage of all the closed claims in the CNA Nurse Practitioner 2012 Liability Update analysis, including 36.5% arising from the physician office setting. Office setting claims also represented a higher average paid indemnity than the overall average due to several high-indemnity paid claims. Almost 75% of the closed claims against NPs were diagnosis-related and treatment and care management-related allegations.” See the chart on page 3 for important risk mitigation plan considerations.

There is no doubt that the addition of nurse practitioners and physician assistants in the team care-delivery model can help address access to care and provide an added benefit to patient care in the office setting by increasing educational opportunities for patients, improving efficiency and increasing patient satisfaction. With the appropriate structure in place to onboard, establish processes and expectations and evaluate the care delivered by NPs and PAs, liability risk to physicians, NPs and PAs can be diminished and our growing patient population care needs met.

Ann Gaffey is SVP, Healthcare Risk Management and Patient Safety for Sedgwick.

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Managing drug samples in physician offices

By KATHLEEN SHOSTEK, RN, ARM, BBA, FASHRM, CPHRM

Managing drug samples in a physician's office or ambulatory care clinic requires a system of checks and balances to help prevent medication errors and adverse drug events, establish a tracking system for alerts and recalls to comply with federal laws and regulations, and to protect from loss of inventory/pilferage.

Also, medication dispensing should be held to equivalent standards of care whether done by a provider office or a pharmacy. Some organizations have stopped distributing sample medications in their provider offices to eliminate the need to manage them or to avoid any legal and ethical issues that can arise when free samples are provided by pharmaceutical company representatives. Others have deemed that the economic benefits to patients and the convenience of starting drug therapy at the time of the visit outweigh the time and effort needed to manage the samples and put sample control systems in place.

The patient safety and liability risks of drug samples include:

- Improper labeling
- Medication errors



- Incomplete patient monitoring
- Lack of appropriate tracking
- Inattention to expiration dates
- Theft

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While handling of pharmaceutical samples by physician offices is largely unregulated, state medical practice acts generally allow physicians and certain other providers with prescribing authority to dispense drugs from their offices. However, from a risk management and patient safety perspective, physician offices that dispense samples need to be sure that patient education is provided and that samples are kept secure from patients and staff who are not authorized to prescribe and dispense them. This is an often-neglected function that Sedgwick consultants find when assessing office practices. Frequently, safeguards are not in place and there is a lack of understanding of safe drug sample management.

Sedgwick's Drug Sample Management Guidance Toolkit offers recommended practices and action steps; see excerpt below.

Sample medications can be important to many patients when managing their health. Whether due to financial issues, limited access to a medication while waiting for a prescription renewal or for the purpose of evaluating the effectiveness of a newly prescribed medication, many physicians feel strongly about providing sample medications to their patients. When managed as outlined below, the handling and distribution of sample medications can be a win-win for patients and providers.

For more information about the Drug Sample Management Guidance Toolkit, contact HealthcareRM@sedgwick.com.

Kathleen Shostek is Senior Healthcare Risk Management Consultant for Sedgwick.

The following recommended practices and action steps, taken from Sedgwick's Drug Sample Management Guidance Toolkit, can be used to help manage drug samples, reduce risk and improve patient safety.

- Assess current sample inventory:
 - Store sample drugs in a locked room with controlled access.
 - Organize samples by type or drug class and place in labeled bins.
- Establish an intake process and use a system to log samples in and out of inventory.
 - Keep a record of each drug by dose, number of samples and lot numbers.
- Educate pharmaceutical company representatives on the required control procedures.
- Assign responsibility for oversight and monitoring of drug samples:
 - Assign responsibility for sample drug inventory inspections. Use a checklist to check for expiration dates, proper bin storage location and deterioration.
 - During inspections, check for recalls and alerts – reconcile with any manufacturer or FDA recalls, market withdrawals and safety alerts (see www.fda.gov).
- Take the following steps when dispensing medications:
 - Access drug reference and/or prescribing software for decision support, safety alerts and drug-drug interaction information.
 - Review patient allergy information and document what sample medications were provided in the patient's chart.
 - Label the medication being dispensed with the following information, avoiding error-prone abbreviations (see www.ismp.org for list of abbreviations to avoid):
 - ✓ Patient name
 - ✓ Medication name
 - ✓ Dosage
 - ✓ Frequency or time
 - ✓ Route
 - ✓ Form (liquid, tablet, drops) and any storage requirements
 - ✓ Date dispensed and provider name
 - ✓ Lot number
 - ✓ Provider name and telephone number

Preventing OR fires: Sedgwick HCRM consultant provides risk manager's perspective

Healthcare Risk Management

Kathleen Shostek, RN, ARM, BBA, FASRHM, CPHRM, Senior HCRM Consultant for Sedgwick, was the risk manager contributor to the "Table Talk" article on the topic of OR Fires for the October 2014 AORN Journal, the peer-reviewed journal of the Association of periOperative Registered Nurses. In the article, Kathy notes, "The adage 'everyone is a risk manager' reflects the collaboration among surgical team members and risk managers that is necessary to establishing best practices in surgical fire safety that are supported without compromise. This collaboration is exemplified in a reliability culture of continuous learning, which embraces safety as a core value and embeds it in the enterprise risk management process so that healthcare organizations can thrive in a changing environment that rewards safe and trusted care." *The full article can be viewed at [http://www.aornjournal.org/article/S0001-2092\(14\)00881-3/fulltext](http://www.aornjournal.org/article/S0001-2092(14)00881-3/fulltext).*

Outpatient care: Safe injection practices for infection prevention

BY KATHLEEN SHOSTEK, RN, ARM, BBA, FASHRM, CPHRM,
SENIOR HEALTHCARE RISK MANAGEMENT CONSULTANT

The majority of infectious disease outbreaks involving hepatitis B and C viruses, HIV virus and bacterial infections have occurred in outpatient and non-hospital settings, involved thousands of patients and were related to unsafe injection practices.^{1,2,3} The costs of these outbreaks in terms of preventable human harm, provider and caregiver liability and legal sanctions have been in the millions.

Investigations into the causes of these outbreaks revealed failures to follow best practices in the following areas:

- Syringe reuse
- Misuse of single-dose/single use vials
- Failure to use aseptic technique
- Unsafe blood glucose testing procedures

According to the Centers for Disease Control and Prevention (CDC), deficiencies identified in outbreaks included a lack of oversight of clinical staff and failure to follow up on reported breaches in infection control practices in outpatient settings.⁴ To ensure that all staff understand and adhere to recommended safe injection practices, infection control procedures and aseptic techniques should be reinforced in training programs, included in policies that are monitored for compliance and validated by random observation of injection practices used by staff.

The CDC publishes recommended practices for safe injections that providers and staff should consistently use in outpatient areas (as well as in hospitals and other non-hospital settings).⁵ These recommended practices include the following:

- Use aseptic technique to avoid contamination of sterile injection equipment.
- Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed. Needles, cannulae and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.
- Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use. Consider a syringe or needle/cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set.
- Use single-dose vials for parenteral medications whenever possible.

- Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use.
- If multi-dose vials must be used, both the needle or cannula and syringe used to access the multi-dose vial must be sterile. Vials should be dated after first access and unused contents discarded within 28 days, or as specified by the manufacturer.⁶ The rubber access port should always be cleaned with an alcohol wipe prior to each access.
- Do not keep multi-dose vials in the immediate patient treatment area and store in accordance with the manufacturer's recommendations; always discard if sterility is compromised or questionable.
- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.
- Infection control practices for special lumbar puncture procedures: Wear a surgical mask when placing a catheter or injecting material into the spinal canal or subdural space.

Additional recommendations for safe diabetes care include:

- Use insulin pens and fingerstick devices for only one patient.
- Dedicate glucometers to a single patient. If glucometers must be shared, clean and disinfect after every use.

The Safe Injection Practices Coalition, along with the CDC, launched the One & Only Campaign to provide information, education, and resources (print materials, audio and video, toolkits, etc.) to healthcare providers and the public to improve injection safety and help prevent the transmission of infections. Access the One & Only website here: <http://oneandonlycampaign.org/content/what-are-they-why-follow-them>. In addition, the CDC website on injection safety can be found here: <http://www.cdc.gov/injectionsafety/>.

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CASE STUDY: Allegations of failure to supervise nurse practitioner in a clinic setting

BY LORI BLACK, SR. PL CLAIMS SPECIALIST AND JANET M. EADS, RN, BSN, LNC, CONSULTANT SR.-PL

Case facts: A patient was brought to the emergency department (ED) by ambulance after having been involved in a motor vehicle accident. Upon the EMS crew's arrival, the patient was awake and alert. His chief complaint was listed as left and right arm pains as well as head hematoma. Full cervical spine precautions were taken. The patient was treated by a Nurse Practitioner (NP) employed by the ED physician group. The patient denied having any loss of consciousness. A small hematoma was noted to his forehead, but it was not bleeding. His pupils were equal and reactive to light. Multiple abrasions were noted and documented on diagrams revealed in the medical record: two bruises on the left side of his forehead and abrasions, one each to his right eye, the bridge of his nose and his chin. A CT scan was not ordered or performed at this time. The patient was released with diagnoses of contusions of the head, scalp abrasion, left wrist ligamentous sprain, status post motor vehicle accident and skin tear of the left wrist.

The patient returned to our insured hospital clinic for follow-up the next day as instructed and was seen by a hospital-employed NP at that time (this NP was subsequently an individually named defendant in a negligence lawsuit). The patient continued to deny any complaints of syncope, dizziness, headache, visual disturbance, loss of consciousness and any seizures, numbness or weakness. The patient remained alert and oriented to person, place and time. The NP noted that the patient had evidence of ecchymosis to his face and head but his pupils remained equal and reactive to light bilaterally. The patient's medication list noted that he was on the anticoagulant Coumadin with an elevated Protime and INR. He was instructed to call with any problems and to follow up with his regular provider in 10 days. It should be noted that the emergency visit record from the previous day did not document that the patient was taking any medications.

Three days later at 02:46, the patient returned to the hospital ED by private vehicle and was diagnosed with moderate to severe neck injury. A CT scan documented an acute subarachnoid hemorrhage and a C-7 fracture. Prior to transfer to another hospital for a higher level of care, the patient required intubation and blood transfusions. He expired later that same day at the receiving hospital.

Allegations: One of the allegations in the lawsuit brought following the patient's death included "failure to supervise" on behalf of the defendant physician. Statutory law in this case states that when a "failure to supervise" claim is premised on the alleged negligence of the underlying person

being supervised, plaintiffs must plead and prove that person was acting outside of the scope of his/her employment. State courts recognize that, otherwise, the claim is really one for vicarious liability. The allegations in this lawsuit did not assert that the NP was acting outside the scope of his employment.

Background: Under the pertinent state law, a Nurse Practitioner is an Advanced Practice Registered Nurse (APRN) who may only practice pursuant to a collaborative practice agreement (CPA) with a physician. It is defense counsel's position that statutes and regulations define the relationship between the APRN and the physician and the mere existence of a CPA neither makes the physician vicariously liable for the APRN's conduct nor imposes any obligations on the physician to train the APRN. The relevant statute states that the APRN may treat patients within the scope of his own practice, i.e., within his own training, experience and skill. The facility involved in this lawsuit maintains a CPA between the NP and physician. That agreement specifically identified a textbook, Clinical Guidelines in Family Practice, as setting out clinical conditions under which the NP could treat and diagnose patients. The insured NP worked as the sole practitioner at the satellite clinic under a CPA. The named physician was in the clinic the day this patient was seen but that physician did not see this patient and the NP did not consult with him on the case. The NP's normal practice was to consult with the physician when a patient had abnormal lab values and/or a very complicated, multi-system issue, neither of which this patient suffered from.

Disposition: This lawsuit is in the early stages of discovery. It is expected that the CPA will insulate the defendant physician since that agreement does not make the physician vicariously liable for the NP nor does the physician have an obligation to train the NP. The NP can essentially work independently and the insured's NP care can be defended.

Risk management considerations: It is important to verify that a mid-level provider such as a Nurse Practitioner has a clear understanding of his or her obligations as part of the care team, including scope of practice, management of ongoing acute problems and methods and frequency of communication with supervising physicians. Regular communication with the supervising physician is advised and should include periodic performance review and chart reviews to evaluate quality of care. For additional risk management tips see: "Nurse Practitioners and Physician Assistants: Managing potential liability in the physician office" on page 1.

UPCOMING EVENTS

Visit the Sedgwick professional liability team at these upcoming conferences:

- **Long-Term Care Risk Legal Forum Summit**
March 4-6 | Las Vegas, NV
visit the Sedgwick booth
- **Virginia Society for Healthcare Risk Management**
April 9 | Charlottesville, VA
Risk Management Mini-Boot Camp – Ann Gaffey
- **Crittenden Medical Insurance Conference**
April 12-14 | Miami, FL
 - *Does Fat Frequency Equal Skinny Severity: The Plight of the Lowly Case Reserve – moderator: Jayme Vaccaro*
 - *Show Me the Data - EHRs Effect on Malpractice Claims – moderator: Jackie Lakins*
- **ASHRM Academy 2015**
April 13-16 | Tampa, FL
 - *Applications Module – faculty: Ann Gaffey (April 15-16)*
 - *Patient Safety II – faculty: Kathy Shostek (April 15-16)*
- **Professional Liability Underwriting Society (PLUS) Medical PL Symposium**
April 28-29 | Atlanta, GA
MedPL: Healthcare Access in Your Big Box Store – moderator: Kathy Shostek
- **National Patient Safety Foundation**
April 29-May 1 | Austin, TX
visit the Sedgwick booth
- **Northern New England Society for Health Care Risk Managers**
May 3-6 | Newport, RI
visit the Sedgwick booth
- **Southern California Association for Healthcare Risk Managers**
May 7 | Palm Desert, CA
Soapbox: The Big Baby Boom Exit-Got Talent? – Jayme Vaccaro
- **Physician Insurers Association of America – Medical Conference**
May 13-15 | Las Vegas, NV
visit the Sedgwick booth
- **RL Solutions User Conference**
June 2-5 | New Orleans, LA
Meaningful Output of Data leads to Actionable Recommendations for Program Improvements – Lynn Gmeiner & Jackie Lakins
- **AHRMNY Annual Educational Conference**
June 5 | New York, NY
visit the Sedgwick booth

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