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CASE OF THE MONTH

Supervision Under Scrutiny: Navigating Physician Assistant Accountability Under MICRA

by Monica Ludwick, Pharm.D.

A mother took her 12-month-old infant daughter, "Olivia," to a dermatology clinic to assess a spot developing on her scalp that was first seen when she was around 8 months old. A physician assistant (PA #1) examined the infant and requested her insurer to approve an "excision and biopsy." One month later, another physician assistant (PA #2) at the clinic saw the patient and performed a "shave biopsy" of the lesion. The doctor who examined the biopsied tissue found no malignancy.

At a follow-up visit, PA #2 noted that Olivia's biopsy wound was healing well and told her mother that there was nothing to worry about. Several months later, Olivia's mother noticed that the lesion was growing back and became concerned. She took Olivia back to the clinic where PA #1 assessed the new growth as "warts" and burned them off with liquid nitrogen.

A few months later, Olivia returned to the clinic because her lesion was "bigger, darker, and varied in color." PA #2 examined the patient, and concluded once again that the growth was warts, and referred her to a general surgeon to have them removed. The general surgeon excised the lesion and provided the tissue to a pathologist, who did not find any malignancy.

About a year later, the patient developed a bump on her neck and began to complain of neck pain. The surgeon removed the neck mass and referred the mother to an oncologist at a children's hospital. The oncologist diagnosed metastatic malignant melanoma. Less than a year later, the patient died—she was a little over four years old.[1]

The patient's mother sued the physicians and the physician assistants (PAs) for the wrongful death of her daughter. The trial court found that both PA #1 and PA #2 had enforceable agency relationships with the supervising physicians, but that they received little to no actual supervision and therefore failed to operate under required supervisory guidelines.

The court further found that the PAs negligently failed to diagnose Olivia's condition or to seek necessary physician guidance. The court awarded the patient's mother $11,200 in economic damages and $4.25 million in noneconomic damages but reduced that amount to $250,000, the maximum allowed at the time under California's Medical Injury Compensation Reform Act of 1975 (MICRA). The court rejected the mother's argument that the MICRA limit was inapplicable to the physician assistants because they violated physician supervision regulations. Olivia's mother filed an appeal.

The Court of Appeal affirmed the application of the MICRA cap in a split decision. California Civil Code

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Section 3333.2 limits the MICRA cap to "services . . . within the scope of services for which the provider is licensed ..." The patient's mother argued that the negligent PAs acted outside that scope—without the required supervision of a physician. The majority disagreed, holding that the PAs acted within the scope of their licenses by having legally enforceable agency agreements with a supervising physician regardless of the quantity, quality, or actuality of that supervision. MICRA's damages cap was therefore properly applied by the trial court. The dissent opined that PAs failed to practice within their license restrictions if they knowingly practiced autonomously without any meaningful physician supervision.[1,2]

The scope of a PA's practice is defined, not by the PA license itself, but by the scope of the practice of the physician who supervises them.

Although there was little to no supervision of the PAs, in this case, there was still a legal relationship with the supervising physicians. It was determined that the PAs acted within the scope of his or her license for purposes of section 3333.2, subdivision (c)(2) if he or she has a practice agreement in place with a supervising physician, regardless of the quality of actual supervision.[2,3]

What supervision is required for a physician assistant?

The supervising physician oversees the activities of and accepts responsibility for the medical services rendered by the PA. The supervising physician is required to adhere to the following mechanisms to provide supervision:[2-5]

- Adherence to adequate supervision as agreed to in a practice agreement that meets the requirements of Business and Professions Code Section 3502.3.
- The physician must, at a minimum, be available by telephone or other electronic communication method at the time the PA examines the patient. (Laws and Regulations - Physician Assistant Board (ca.gov))
- Section 1399.541 of Title 16 of the California Code of Regulations specifies when a physician is required to be "immediately available" as defined, such as acting as first or second assistant in surgery.

What elements should the Practice Agreement contain?

Senate Bill 697 (SB 697) was enacted four years ago. It requires a practice agreement between a PA and a physician that meets specified requirements. The agreement must address policies and procedures to ensure adequate supervision of the physician assistant, including, but not limited to, appropriate communication, availability, consultations, and referrals between a physician and the PA in the provision of medical services. The practice agreement must also establish policies and procedures to identify a physician and/or surgeon (with privileges to practice in that hospital) who is supervising a PA rendering services in a general acute care hospital. SB 697 also provides that any reference to a "delegation of services agreement" in any other law means "practice agreement," as defined.

The legislation further clarifies that supervision does not require the supervising physician to be physically present, but does require adequate supervision as agreed to in the practice agreement and requires the physician and surgeon be available by telephone or other electronic communication method at the time the PA examines the patient. However, it also prohibits this provision from being construed as barring the Physician Assistant Board from requiring the physical presence of a physician as a term or condition of a PA's reinstatement, probation, or imposing discipline.[3,5]

Risk management strategies

On May 23, 2022, Assembly Bill 35 (AB 35) was signed into law by Governor Gavin Newsom. AB 35 altered many of the protections and limits provided by MICRA by raising the number of caps and amounts on noneconomic damages in medical malpractice lawsuits—possibly inviting an increase in the frequency and cost of claims.

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Therefore, it is more important now than ever for physicians to review their physician assistant practice agreements:

Legal Compliance: Physician assistant practice agreements outline the scope of practice for physician assistants, specify the tasks they can perform, and the methods for evaluating qualifications and competency, and set forth the level of supervision required. By reviewing these agreements and updating them when necessary, physicians can ensure that the tasks delegated to PAs are within their authority and comply with state laws and regulations.

Quality of Care: PAs play a crucial role in providing healthcare services. By reviewing the practice agreements, physicians can ensure that the delegated tasks align with the skills and expertise of the physician assistant. This helps maintain the quality of care provided to patients.

Patient Safety: PAs work closely with physicians in diagnosing and treating patients. Reviewing practice agreements allows physicians to ensure that appropriate levels of supervision are in place, minimizing the risk of errors or inadequate patient care.

Professional Responsibility: Physicians have a professional responsibility to supervise and oversee the work of PAs. By reviewing practice agreements, physicians can fulfill this responsibility and ensure that the physician assistant is practicing within the agreed-upon guidelines.

Liability Protection: In the event of malpractice claims or legal disputes, practice agreements can help physicians demonstrate that they have provided adequate supervision and oversight to physician assistants. This can help protect physicians from potential liability and legal consequences.

In summary, reviewing physician assistant practice agreements and executing the required actions are crucial for legal compliance, maintaining quality of care, ensuring patient safety, fulfilling professional responsibilities, and protecting against liability.

Monica Ludwick, Pharm. D., is a Senior Risk Management and Patient Safety Specialist. Questions or comments related to this article should be directed to MLudwick@CAPphysicians.com.

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2024 Disclosure Statement Now Available

Each year, we publish the Disclosure Statement, which gives an overview of operations for the Cooperative of American Physicians, Inc. (CAP) and the Mutual Protection Trust (MPT) pursuant to California Insurance Code Section 1280.7.

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Beyond Documentation: The Essential Role of Incident Reports in Medical Practices

by Rikki Valade RN, BSN, PHN

The healthcare industry has been searching for ways to improve patient safety since the release of the Institute of Medicine's (IOM) *To Err is Human* report on November 29, 1999.[1] Incident reporting and tracking are important elements of healthcare that enhance patient safety and quality of care.[2] Incident reporting should be part of every healthcare setting, including office-based care settings. Unforeseen circumstances such as safety events, adverse events, and unexpected complications can and do occur. Although most of us believe "it will never happen to us," it is important to anticipate the unexpected.[1]

An incident report provides a standardized method for documenting and addressing events that may involve a patient, visitor, or employee that are outside the normal day-to-day activities.[3] Although this article will focus on patient safety incident reporting, it is important to also have a process for incident reporting involving visitors and employees.

A patient safety event is an incident or condition that could have resulted, or did result, in harm to a patient.[4] Patient safety events include, but are not limited to medication errors, allergic reactions to medications, falls, infections, procedure complications, misdiagnosis, delay in diagnosis, or any other unexpected event that compromises the safety or well-being of a patient. The California Medical Association (CMA) indicates the primary focus of patient safety event reporting is to identify, analyze, and prevent such incidents from happening again to enhance patient safety and quality of care.[5]

Incident Reports help us:[2]

- **Learn from mistakes** by identifying trends, analyzing root causes, and making changes to prevent similar incidents in the future.
- **Track progress** by measuring improvements over time. This allows proactive actions to create a safer environment.
- **Track trends** for any reoccurring issues and/or trends that may point to a larger problem.
- **Improve risk management** by taking proactive action to minimize risk exposure.
- **Take actionable steps** by deciding follow-up actions to prevent future incidents. This may include changes to policies and procedures.

ECRI conducted a study of safety events occurring in office-based settings, including ambulatory care centers, community health centers, and primary care provider offices.[6] The safety events fell into four main categories:[6]

1. Diagnostic testing errors
2. Medication events
3. Falls
4. Security or safety incidents, such as workplace violence.

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The Incident Report

Incident reporting is the most common method of risk identification. Developing an incident reporting policy should be a priority, beginning with an incident form that is easy to use and understand. The form should capture the following information:[7]

- Date of incident
- Time of incident
- Type of incident
- Location of incident
- Individuals involved
- Witnesses
- Detailed description of the incident
- Any injuries sustained
- Photo evidence of the incident
- Action taken to address the incident
- Assistance services provided to patient
- Outcome of the patient (e.g., transported by paramedics to the hospital; transported home with son, left on own accord in no distress)

The practice should ensure that all staff are trained in incident reporting procedures and understand their roles and responsibilities. Training should emphasize the importance of reporting incidents promptly and accurately without fear of reprisal. By simplifying the process of reporting incidents, you enable your employees to embrace their mistakes, learn from them, and advance in their professional development.[7]

Incident reports are internal documents and should never be given to the patient and/or family, nor added to the patient's health record.[3] They are confidential documents that should be used for investigation and internal process changes to improve patient safety. Think of the incident report as a tool to continuously improve your process.[3] Adhere to patient confidentiality guidelines when documenting patient safety events. Only share information on a need-to-know basis and store the documentation in a secure location, whether physical or digital.

The Medical Record

Ensure that a clear and concise summary of the incident is documented in the patient's medical record. The documentation should be brief and factual. Include relevant details such as the nature of the event, actions taken, and any follow-up measures. Record any conversations or interactions with the patient or their family regarding the safety event. This includes discussions about the event itself, questions by the patient and/or family, and any actions or recommendations provided to address the event. Follow the guidelines below:[8]

- Document only objective observations or known facts.
- Complications that were manifested during care should be reflected.
- Document specifically what the patient/family was told.
- Do not blame other professionals or facilities in the medical record.
- Do not use defensive or blaming documentation.
- Do not change anything previously written. An addendum may be included as facts become available by dating the addendum on the day it is written.
- Do not document the call to your professional liability carrier.
- Do not document that an incident report was completed.

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Be mindful that others, including your patient, may read your documentation.

You should also note some safety events that occur in office-based settings that have mandatory and/or voluntary reporting requirements to outside regulatory agencies:

OSHA Reporting Requirements	**OSHA Recordkeeping and Reporting**
VAERS-Vaccine Adverse Event Reporting	**VAERS Reporting**
Mandatory Patient Notification of Sterile Compounded Drug Recalls by Pharmacies, however the Business & Professions **Code §4126.9 states**: If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.	**Business & Professions Code §4126.9**
Voluntary Reporting of Adverse Events involving Medication(s) or Medical Device	**FDA MedWatch**

In summary, remember that incident reports play a pivotal role in patient safety. By documenting and tracking safety events, you will be able to understand and identify patient safety concerns in your office-based setting, anticipate issues, and address them to reduce your risk exposure. Incident reports help identify areas for improvement, help identify preventative measures, and ultimately enhance patient safety and quality of care provided by your medical practice.

Check with your medical professional liability carrier regarding discoverability of incident reports.

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Lame Ducks and Pay Cuts

by Gabriela Villanueva

After each presidential election, Congress holds its lame duck session before the new congressional term begins. This time is used by lawmakers to resolve unfinished business from a regular session or deal with specific and/or urgent items.

This year, Congress will need to address several issues, including the 12 major appropriation bills that fund and keep the federal government open past December 20th, and other policy issues that require some kind of action or face expiration of various legislative authorities at the end of the calendar year.

For physicians, no issue is more urgent than the Medicare Physician Fee Schedule (MPFS) and the current proposed 2.8% physician pay cut. Slated to go into effect on January 1, 2025, the cut marks the fifth consecutive year that the Centers for Medicare and Medicaid Services (CMS) has lowered payments to physicians and other clinicians.

This situation is in part the result of payment reforms made in the 2015 Medicare Access and CHIP Reauthorization Act (MACRA). Among other provisions, MACRA did not account for annual inflation of physician payments, based on an assumption that physicians would be able to earn bonuses through the Merit-based Incentive Payment System (MIPS). Because MIPS has not produced the anticipated bonuses, the 2.8% proposed pay cut would be detrimental to physician practices already grappling with high inflation rates.

A bipartisan majority of the House of Representatives—232—has signed onto a letter that urges House leadership to "expeditiously pass legislative fixes" that stop a "harmful" 2.8% Medicare physician payment cut slated for January 1 and give physicians a payment update "that takes into account the cost of actually delivering care to patients."[1] It is hoped that the inflation adjustment issue can also be addressed. However, this may be difficult in the year-end session and may carry over into 2025 when a more comprehensive reform of physician pay can be considered.

There has already been a lot of work done to lay a foundation for action. The issue carries strong bipartisan support and therefore, a strong likelihood of obtaining a desirable outcome—eventually.

Gabriela Villanueva is CAP's Government and External Affairs Analyst. Questions or comments related to this article should be directed to GVillanueva@CAPphysicians.com.

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What Every Medical Practice Needs To Know About Credit Card Processing

Credit card spending has more than tripled in the last decade. For merchants accepting credit cards, that means billions of dollars in processing fees. While processing may be big money, very few businesses understand the ins and outs of the industry or the issues they should be aware of when selecting their service.

Software Integration Issues

Many practices use a point-of-sale solution with integrated software. Typically, these software companies work exclusively with one processor, which can make it challenging for a business to secure optimal rates on their own.

Another major issue can be the software itself. If you aren't running the most recent upgrade (which may not be automatic and require an opt-in for install), all the information required by the processor at the time of the transaction may not be shared, resulting in additional charges that can really add up.

Chargebacks

A chargeback happens when the credited amount from the initial charge to your business checking account is reversed. The issuing bank reverses all or a portion of the transaction amount to your acquirer/processor, citing a violation of Payment Card Networks rules or regulations as the reason for the chargeback. This often occurs frequently for businesses who have a monthly membership program. Other reasons for chargebacks include suspected fraudulent activity with the card, non-receipt of the product or service, or cardholder disagreement regarding the quality/receipt of merchandise.

Managing chargebacks and engaging in representment can significantly reduce your expenses and improve your ratios, but these processes demand a considerable amount of time and resources. If you'd like to do so, check if your processor has a chargeback dispute manager tool.

Respond or Be Fined

In the past, merchants could disregard a response request, essentially defaulting to accepting the chargeback. No longer! To expedite the process, Visa has introduced time constraints. Failure to respond promptly will result in fines.

Unclear Guidelines Around Surcharges

Some business owners have turned to cash discounts and surcharges to cover increases in processing costs, passing the cost to their customers. The guidelines and laws surrounding these programs are unclear, ever-changing, and vary by state and area. Many states cap the percentage of a transaction merchants can charge and the surcharge itself is often set up incorrectly, leading to math errors and overcharging. There are serious tax implications and the possibility of fines in these cases, not to mention insurance constraints.

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Be sure to sign up for a registered surcharge program that only passes the fee on credit cards and enlist the help of a vigilant auditing service or work with an expert who can help decipher these confusing statements and negotiate lower fees.

PCI and HIPAA Compliance

Though HIPAA compliance covers medical and personal data, it does not cover credit card payment information. While the specific data they pertain to varies, there is some overlap between HIPAA and PCI in implementation.

Every merchant that stores, processes, or transmits cardholder data is responsible for its protection. The Payment Card Industry (PCI) Data Security Standard (DSS) was created to help protect consumer data. The good news is that it's easy to become compliant by using a PCI-compliant hosting provider. Europay, MasterCard, and Visa (EMV) chip cards are an additional way to protect card-present transactions.

Medical practices must remain wary, and PCI compliance should never be ignored. Not only will the fines negatively affect your bottom line, but not becoming compliant could bankrupt your practice and ruin your reputation should there be a breach.

How To Remain PCI Compliant

To ensure PCI compliance, you must implement the proper security policies, procedures, and staff training. You can start by auditing your merchant statements, which will show noncompliance via a penalty fine.

Other simple steps include changing your user account passwords on a regular basis, using a third party to monitor your network security, and reviewing your physical security measures such as employee training and information technology (IT) infrastructure.

Protecting the Interests of Your Business & Your Customers

The ever-evolving landscape of credit card security and compliance underscores the need for constant vigilance to safeguard your financial interests. Increasing awareness leads to savings and less stress down the line and empowers business owners to navigate the credit card payment ecosystem with greater confidence

Third-party auditors are often the best resources for understanding the credit card processing ecosystem, as processors often hide fees and make calculation errors, needlessly confusing monthly statements. It's also normal for them to raise rates three to four times per year. Without due diligence and knowing how to read these statements, fees add up quickly.

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Ask My Practice

By Andie Tena

The Impact of Direct Primary Care

Direct primary care (DPC) is a practice model that is quickly gaining popularity among primary care practitioners and patients across the country.

From 2017-2021, the number of active DPC clinicians per 100,000 people increased 159% in comparison to only a 6% increase overall in primary care providers per 100,000 people. Additionally, DPC memberships are seeing an average annual growth of 36%, reaching a total growth rate of 241% from 2017-2021.[1]

There is good reason for this surge. Instead of using traditional insurance, patients pay their primary care physician a flat monthly or annual fee, under terms of a contract, in exchange for a broad range of primary care and medical administrative services that include office visits, lab tests, basic procedures, and more.[2] Under the DPC model, physicians can rely on a stable revenue stream without involving insurance companies or third-party payers. As result, they can provide a higher level of comprehensive and personalized primary care services to their patients.

DPC allows patients to have a direct relationship with their primary care physician and improved access to their needed services and treatment, all while potentially paying less out-of-pocket costs.

Other components of a DPC practice model:

Benefits to Physicians

- The DPC model allows primary care physicians to operate independently, without the administrative burden and restrictions imposed by insurance companies, enhancing job satisfaction and reducing physician burnout.
- The DPC model can foster a stronger doctor-patient relationship, as patients have more frequent and unhurried visits with their primary care physician, leading to better communication and trust.
- DPC doctors often have more flexibility in prescribing medications, as they are not bound by insurance formularies and can focus on choosing the most appropriate treatment for their patients.
- DPC can also reduce overall healthcare costs by minimizing unnecessary specialist referrals, emergency room visits, and hospitalizations through proactive and preventive care.

Benefits to Patients

- DPC focuses on preventive care and wellness, aiming to keep patients healthy and address health issues early on before they become more serious and costly.

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- DPC doctors have smaller patient panels, which allows them to offer same-day or next-day appointments, extended office hours, and even virtual consultations, improving access to care.
- DPC can be particularly beneficial for individuals with chronic conditions who require ongoing and specialized care, as they can receive comprehensive primary care services from a single provider.
- DPC can lead to cost savings for patients, as they only pay a fixed monthly or annual fee instead of copays and deductibles for each office visit or service.

For small businesses and self-employed individuals who want to provide healthcare benefits to their employees without the complexity and high costs of traditional insurance plans, DPC can be a viable option.

It is important to note that DPC is not a substitute for health insurance, as it does not cover specialty care, hospitalizations, or emergencies. Patients are encouraged to have a catastrophic insurance plan to cover these situations.

The DPC model addresses many of the challenges present in today's healthcare system, including high costs, barriers to quality ongoing care, physician burnout, and complex insurance administration and billing.

Some critics argue that DPC may lead to a two-tiered healthcare system, where those who can afford to pay for direct primary care receive better access and quality of care compared to those who rely on traditional insurance. Additionally, DPC may face regulatory challenges in some states, as insurance laws and regulations are not always tailored to accommodate this model.

However, through various organizations, efforts are being made to create a more favorable environment for DPC practices.

Learn more at:

The California Direct Primary Care Coalition: **www.calidpc.com**

The Direct Primary Care Coalition: **www.dpcare.org**

Andie Tena is CAP's Assistant Vice President of Practice Management Services. Questions or comments related to this column should be directed to ATena@CAPphysicians.com.

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