The Dark Side of Community Paramedicine:
Liability and Risk Management in Mobile Integrated Healthcare

Presented by
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Doug Wolfberg is a founding partner of Page, Wolfberg & Wirth, and one of the best known EMS attorneys and consultants in the United States. Widely regarded as the nation's leading EMS law firm, PWW represents private, public and non-profit EMS organizations, as well as billing companies, software manufacturers and others that serve the nation's ambulance industry. Doug answered his first ambulance call in 1978 and has been involved in EMS ever since. Doug became an EMT at age 16, and worked as an EMS provider in numerous volunteer and paid systems over the decades. Doug also served as an EMS educator and instructor for many years.

After earning his undergraduate degree in Health Planning and Administration from the Pennsylvania State University in 1987, Doug went to work as a county EMS director. He then became the director of a three-county regional EMS agency based in Williamsport, Pennsylvania. He then moved on to work for several years on the staff of the state EMS council. In 1993, Doug went to the nation's capital to work at the United States Department of Health and Human Services, where he worked on federal EMS and trauma care issues. Doug left HHS to attend law school, and in 1996 graduated magna cum laude from the Widener University School of Law. After practicing for several years as a litigator and healthcare attorney in a large Philadelphia-based law firm, Doug co-founded PWW in 2000 along with Steve Wirth and the late James O. Page. As an attorney, Doug is a member of the Pennsylvania and New York bars, and is admitted to practice before the United States Supreme Court as well as numerous Federal and state courts. He also teaches EMS law at the University of Pittsburgh, and teaches health law at the Widener University School of Law, where he is also a member of the school's Board of Overseers.

Doug is a known as an engaging and humorous public speaker at EMS conferences throughout the United States. He is also a prolific author, having written books, articles and columns in many of the industry's leading publications, and has been interviewed by national media outlets including National Public Radio and the Wall Street Journal on EMS issues. Doug is a Certified Ambulance Coder (CAC) and a founder of the National Academy of Ambulance Coding (NAAC). Doug also served as a Commissioner of the Commission on Accreditation of Ambulance Services (CAAS).

The Dark Side of Community Paramedicine

Liability and Risk Management in Mobile Integrated Healthcare

Page Wolfberg & Wirth
The National EMS Industry Law Firm®

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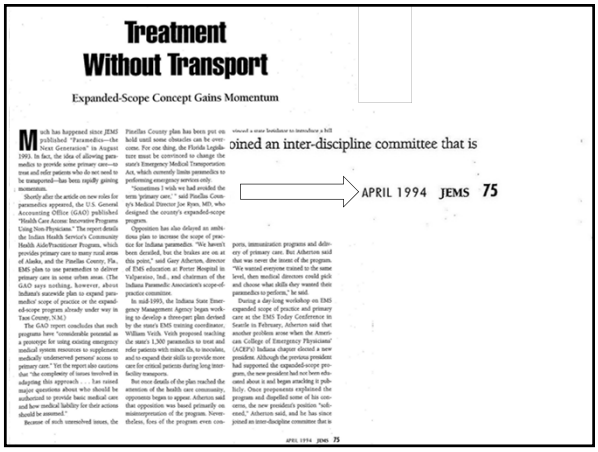
MIH Defined

In its simplest definition, Mobile Integrated Healthcare (MIH) is the provision of healthcare using patient-centered, mobile resources in the out-of-hospital environment. It may include, but is not limited to, services such as providing telephone advice to 9-1-1 callers instead of resource dispatch; providing community paramedicine care, chronic disease management, preventive care or post-discharge follow-up visits; or transport or referral to a broad spectrum of appropriate care, not limited to hospital emergency departments.

-Vision Statement on Mobile Integrated Healthcare and Community Paramedicine, NAEMT et al.

Is This *Really* All That New?



Treatment Without Transport

Expanded-Scope Concept Gains Momentum

With has happened since JEMS published "Paramedics—the Next Generation" in August 1993. In fact, the idea of allowing paramedics to provide some primary care—to treat and refer patients who do not need to be transported—has been rapidly gaining momentum.

Shortly after the article on new roles for paramedics appeared, the U.S. General Accounting Office (GAO) published "Health Care Access: Innovative Programs Using Non-Physicians." The report details the Indian Health Service's Community Health Aide/Practitioner Program, which provides primary care to many rural areas of Alaska, and the Pinellas County, Fla., EMS plan to use paramedics to deliver primary care in some urban areas. (The GAO says nothing, however, about Indiana's statewide plan to expand paramedics' scope of practice or the expanded-scope program already under way in Taos County, N.M.)

The GAO report concludes that such programs have "considerable potential as a prototype for using existing emergency medical system resources to supplement medically underserved persons' access to primary care." Yet the report also cautions that "the complexity of issues involved in adopting this approach . . . has raised major questions about who should be authorized to provide basic medical care and how medical liability for their actions should be assessed."

Because of such unresolved issues, the Pinellas County plan has been put on hold until some obstacles can be overcome. For one thing, the Florida Legislature must be convinced to change the state's Emergency Medical Transportation Act, which currently limits paramedics to performing emergency services only.

"Sometimes I wish we had avoided the term 'primary care,' " said Pinellas County's Medical Director Joe Ryan, MD, who designed the county's expanded-scope program.

Opposition has also delayed an ambitious plan to increase the scope of practice for Indiana paramedics. "We haven't been derailed, but the brakes are on at this point," said Gary Atherton, director of EMS education at Porter Hospital in Valparaiso, Ind., and chairman of the Indiana Paramedic Association's scope-of-practice committee.

In mid-1993, the Indiana State Emergency Management Agency began working to develop a three-part plan devised by the state's EMS training coordinator, William Voth. Voth proposed teaching the state's 1,200 paramedics to treat and refer patients with minor ills, to inoculate, and to expand their skills to provide more care for critical patients during long interfacility transports.

But once details of the plan reached the attention of the health care community, opponents began to oppose. Atherton said that opposition was based primarily on misinterpretation of the program. Nevertheless, foes of the program even convinced a state lawmaker to introduce a bill

oined an inter-discipline committee that is

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ports, immunization programs and delivery of primary care. But Atherton said that was never the intent of the program. "We wanted everyone trained to the same level, then medical directors could pick and choose what skills they wanted their paramedics to perform," he said.

During a day-long workshop on EMS expanded scope of practice and primary care at the EMS Today Conference in Seattle in February, Atherton said that another problem arose when the American College of Emergency Physicians' (ACEP's) Indiana chapter elected a new president. Although the previous president had supported the expanded-scope program, the new president had not been educated about it and began attacking it publicly. Once proponents explained the program and dispelled some of his concerns, the new president's position "softened," Atherton said, and he has since joined an inter-discipline committee that is

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We've been down this road before as an industry.

How can this time be different?

Long-Term MIH Sustainability Requires:

- Stakeholder buy-in
  - Will community accept re-purposing its EMS resources?
  - Will local elected officials tolerate response time tradeoffs for improved and integrated primary care coordination?

Long-Term MIH Sustainability Requires:

- Reliable and consistent funding
  - Volume-based fee-for-service model vs. value-based population model
  - The challenges will be to *prove* that MIH makes a real difference
  - This will require new metrics and reliable data

Long-Term MIH Sustainability Requires:

- A cultural shift
  - From a "public safety" culture to a "population health" culture

MIH Culture

- Successful MIH implementation requires a cultural shift
- If your agency views MIH as integral to its mission, the odds of long-term sustainability increase dramatically

MIH Culture

- On the other hand, if MIH is viewed as a bandwagon to climb on, the chances of long-term sustainability are greatly reduced

Long-Term MIH Sustainability Requires:

- A different breed of provider
  - Recognition that the delivery of MIH requires a different clinical and interpersonal skill set than traditional EMS

MIH Models

Readmission Reduction Model

Readmission Reduction

- MIH program works in conjunction with hospitals to provide targeted services to patients who are discharged with specific conditions
- Goal is to reduce preventable readmissions

HRRP

- Section 3025 of the ACA
- Penalizes hospitals for excess readmission rates within 30 days of discharge
- Penalties up to a max of 3% of Medicare reimbursement

Conditions

- These conditions are currently covered under the HRRP:
  - Acute myocardial infarction
  - Heart failure
  - Pneumonia
  - COPD
  - Elective hip and knee replacements

HRRP & MIH

- HRRP motivates hospitals to better manage ongoing needs of patients at discharge and outside of hospital to avoid readmission
- MIH programs can demonstrate cost-savings to hospitals by providing services that reduce preventable readmissions

MIH Services – Readmission Reduction

- Evaluation of compliance with discharge plans
- Facilitating medication refills and monitoring med regimen and potential drug interactions
- Patient assessment of designated clinical parameters

MIH Services – Readmission Reduction

- Scheduling and reminders of follow-up doctor appointments
- Transportation (or facilitating transportation) for appointments
- Patient education

Frequent EMS User Model

Frequent EMS User Model

- Protocol-driven with concurrent and retrospective medical oversight
- Designed to reduce 911 utilization and ambulance transport for high-frequency but non-acute conditions

Conditions

- The conditions for MIH services in a Frequent EMS User Model must be carefully evaluated and selected with medical director involvement
- Must be conditions in which the CP can make clinical judgments with high degree of confidence

Conditions

- Some studies have suggested that EMS providers don't always do a good job differentiating between pts who require transport and those who don't
- Monitoring outcomes is critical

Follow-up

- Frequent EMS User Model requires appropriate follow-up with patients to ensure hospital evaluation not required
- Re-evaluate conditions included in the model, and the applicable protocols, based on continuous quality improvement program

Pathways to Alternate Care

- The MIH agency will have to identify and coordinate with other appropriate sources of care
  - Mental health
  - Substance abuse/addition counseling
  - Social work
  - Primary care
  - Etc.

Primary Care/ Physician Extender Model

Physician Extender Model

- Typically involves expanded scope of practice
  - State law considerations
  - Service medical director considerations
- This model is more prevalent in rural/super rural areas

Physician Extender Model

- May involve more traditional primary care services
  - Labs/field diagnostics
  - Vaccines
  - Wellness checks

Other MIH Models

- 911 Nurse Triage Model
  - Relatively small percentage of current MIH programs (8% according to NAEMT survey data)
- Alternate Destination Referral Model
  - Often implemented in conjunction with Frequent EMS User Model

Selecting Your MIH Model(s)

- Selection of appropriate MIH program model(s) must begin with a forthright community health needs assessment
- Cannot be based on a mere desire to "get involved" in MIH
  - MIH programs must fill unmet needs

Other Model Selection Factors

- Availability of MIH-trained providers
- Availability of equipment/resources
- Community/stakeholder buy-in
- Competitive landscape
- Regulatory environment
- Liability assessment
- Insurance availability

To what degree does your model align with your mission?

Model vs. Mission

- Primarily all-911 agencies or traditional public safety agencies may find that Frequent EMS User or Alternate Destination models are a better "fit"
- Hospital-based ambulance services may find that Readmission Reduction Model is a good fit

Model vs. Mission

- But, one size doesn't fit all
- No "right or wrong" answers
- The beauty of this is that it's *community-based*, so the needs of *your* community's healthcare system are the primary driver

Legal Considerations in MIH Programs

The Anti-Kickback Statute

- Prohibits knowing and willful solicitation or receipt of any remuneration, either directly or indirectly, in cash or in kind, to induce referrals of items or services reimbursable by the Federal health care programs

42 U.S.C.A. Section 1320a-7b

The Anti-Kickback Statute

- AKS protects against overutilization
  - Financial incentives for referrals results in the creation of artificial demand
  - Drives up health care costs
  - Encourages unnecessary services

The AKS Applies to Both Sides of the Transaction

This means that the ambulance service and the facility are both on the hook

The Anti-Kickback Statute

- Penalties for Violation
  - Civil Monetary Penalties
    - Up to $25,000 in fines *per violation*
    - Plus up to $50,000 in civil monetary penalties (CMPs) *per violation*
    - Amount depends upon specific section violated

The Anti-Kickback Statute

- Penalties for Violation (cont'd)
  - Exclusion from Medicare
  - Criminal penalties
    - Up to five years imprisonment

MIH Compliance

- Be sure to address AKS compliance in all aspects of your MIH arrangements
- This is particularly important where you enter into an MIH arrangement with an entity that is also a source of referrals of traditional ambulance transportation services

Offer ⇔ Solicitation

Example: ABC Ambulance offers free MIH services for post-discharge patients of XYZ Hospital if the Hospital selects ABC as its primary provider for discharges and interfacility transports.

XYZ Hospital refuses the offer.

ABC Ambulance may still have committed an AKS violation.

Payment ⟷ Receipt

Example: ABC Ambulance provides MIH and transport services for XYZ Hospital. ABC offers to have its Community Paramedics perform services for the Hospital in between patient visits at no charge to the Hospital. The Hospital accepts.

Both ABC Ambulance and XYZ Hospital may have violated the AKS.

MIH AKS Compliance

- Advisory Opinion 13-10
  - First OIG opinion to address contracting for HRRP services between potential referral sources

OIG Advisory Opinion 13-10

- Healthcare company owned by a drug manufacturer contracted with hospitals to provide technology platforms and services to:
  - Coordinate care
  - Help pts adhere to their discharge plans
  - Avoid preventable hospital readmissions

OIG Advisory Opinion 13-10

- Discharge nurse functions:
  - Identifies a pt who meets the eligibility criteria (i.e., one of the HRRP conditions)
  - Explains the post-discharge services to the pt
  - If pt elects to participate in the program, the nurse uploads the pt info into the company's software platform

OIG Advisory Opinion 13-10

- Patient Liaison (not medically trained) functions:
  - Remind pts of appointments
  - Help them obtain transportation
  - Furnish educational materials
  - Remind pts to refill their prescriptions*
    - * Since the company is owned by a drug manufacturer, one of the reasons that potential AKS issues arose

OIG Advisory Opinion 13-10

- If the liaison believes the pt requires a healthcare consult, liaison contacts the health care provider designated by the patient*

*Another potential area where referrals and AKS issues can arise

OIG Advisory Opinion 13-10

- Three types of fees paid under this arrangement:
  (1) **Flat fees** – paid by hospital to cover implementation of the software platform, electronic health record integration, etc.
  (2) **Per-pt annual fees** – to cover ongoing technology and personnel costs
  (3) **Hourly fees** – to cover additional optional services the hospital might purchase from the company

OIG Advisory Opinion 13-10

- OIG's conclusion:
  - "Although the Proposed Arrangement could potentially generate prohibited remuneration under the AKS if the requisite intent to induce or reward referrals…were present, the OIG would not impose administrative sanctions…in connection with the Proposed Arrangement."

OIG Analysis

- **First** – unlikely to lead to increased costs; could encourage *appropriate* utilization and reduce readmissions, thus saving money
- **Second** – unlikely to interfere with clinical decision making; would apply only to pts after they are discharged, and only with certain, identified conditions

OIG Analysis

- **Third** – safeguards built into the program to prevent it from being used to increase drug sales by the parent company
- **Fourth** – the arrangement is unlikely to result in inappropriate patient steering; referrals for healthcare services are made only to providers designated by the patient

EMS Implications

- This Advisory Opinion not EMS-specific, but provides a compliance "blueprint"
  - First time OIG has addressed (and approved) a fee-based arrangement for post-discharge services designed to reduce preventable hospital readmissions

EMS Implications

- EMS extremely well-positioned to provide many of these types of services
  - Arranging transportation when needed
  - Recognizing conditions which may warrant further evaluation
  - Monitoring medication compliance
  - Assisting with medication administration
  - Providing patient education

EMS Implications

- EMS is already a participant in the patient's continuum of care
  - EMS may have originally transported the patient when admitted, perhaps even upon discharge

EMS Implications

- But, because the EMS agency may provide multiple lines of service to a healthcare facility – some of which the ambulance service can bill separately to Medicare – the AKS can be implicated

The Big Picture

- The OIG and other enforcement agencies will not simply view the MIH program standing alone
- They will examine the totality of the arrangements in place between referral sources

Example

- If an ambulance service provides discharge and interfacility transports for a hospital, and prices its MIH services below cost, the MIH services (which benefit the hospital through readmission reduction) could be seen as an inducement to select that ambulance service

MIH Pricing

- So, even though the MIH services are not separately reimbursable by Medicare, the MIH agency must ensure that they are priced appropriately
- Below cost services are inherently suspect under the AKS

Cost Analysis

- MIH agencies must determine their costs for the various lines of MIH services they offer
- Retain appropriate cost analysis documentation in your files

Cost Analysis

- Obtain advice of qualified accountant
- Update the cost analysis periodically
- Consider direct and indirect costs and overhead

Cost Analysis

- This can help reduce the possibility that pricing for MIH services can be seen as an inducement for the referral of Medicare-covered transports

Other MIH Legal Considerations

Other MIH Program Considerations

- Documentation
- Liability
- Insurance
- Regulatory Issues
- Pay Practices

MIH Patient Care Documentation - A New Approach?

Documentation of CP "Encounters"

- Weakness of Traditional PCRs
- Need for Focus on "Body Systems" and "Activities of Daily Living"
- Psychological Assessment
- Assessment of the Home Environment and Family Relations

Documentation of CP "Encounters"

- Interaction with Other Health Care Providers
- More akin to "Nurse's Notes"
- Documentation of Assessment, Treatments, and *Patient Instructions* Given

Liability Issues

- Economic sustainability of the Readmission Reduction Model of MIH is centered on keeping patients *out* of the hospital within 30 days after discharge
- What about those patients who *require* re-hospitalization during that period?

Liability Issues

- Strong economic incentive to avoid pt readmissions
- However, remember that MIH programs will be answerable in tort law for their role in making those decisions in a negligent manner

MIH Standards of Care

- Although some practice standards exist, the applicable MIH standard of care could be a moving target

MIH Risk Management

- MIH programs may not enjoy the same legal protections that traditional EMS delivery receives
  - EMS Act qualified immunity
  - "Good Samaritan" immunity
  - Individual and agency protections

Liability Protection

- Whether qualified immunity exists may depend upon the type of services being provided
  - Readmission Reduction Model - scheduled home visits – may not be immune from liability
  - Frequent EMS User Model - 911 responses with no transport *may* be covered

State Law

- The nature and extent of liability protections and immunity statutes is determined by state law
- Obtain qualified legal counsel to advise your agency on liability issues for your MIH program

Insurance

- Work with your insurance agent or broker to ensure that your MIH program is adequately insured
- May require riders to existing professional and general liability policies
  - Also, auto, workers comp, etc.

Insurance

- *Public agencies* – be careful here!
- Some state laws waive immunity for local governments to the extent they acquire insurance for their activities

MIH Risk Management

- MIH program must have peer review and physician oversight mechanisms to ensure appropriate clinical decisionmaking

MIH Risk Management

- If a patient requires readmission, they should be readmitted based on clinical considerations – not financial ones

EMS Regulatory Issues

- MIH programs are very much coming from the bottom up – not the top down
- As a result, many states do not have laws, regulations, policies or protocols in place regarding MIH

MIH Legal Authority

- In some states, the legal authority under which MIH programs may operate is not entirely clear
- Some states "tolerate" or "accept" it – but few expressly "permit" it

MIH Legal Authority

- May be MIH model-dependent
  - Home-based models (Readmission Reduction, Physician Extender) – these models are "less EMS" and more "primary care"
  - The further the model gets from "traditional EMS," the less likely your state EMS office will know how to handle it

MIH Legal Authority

- May be MIH model-dependent
  - 911-based models (Frequent EMS User, 911 Nurse Triage) – these models are "more EMS" and less "primary care"
  - These models may more closely align with existing EMS laws, regulations, policies and protocols

Scope of Practice Issues

- Regulatory compliance with an MIH program may depend upon whether your model involves expanded scope of practice

Expanded Scope

- Requires a close examination of the options – if any – under state EMS act
  - Local option expanded scope?
  - Demonstration/research/pilot project?
  - Case-by-case approval?

Other Laws

- You may not necessarily be limited to whether or not your MIH program can squeeze into existing EMS laws/regulations

Example – PA Medical Practice Act

(a) General rule.--A medical doctor may delegate to a health care practitioner or technician the performance of a medical service if:

(1) The delegation is consistent with the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth.

(2) The delegation is not prohibited by regulations promulgated by the board.

(3) The delegation is not prohibited by statutes or regulations relating to other licensed health care practitioners.

Legal Basis for MIH

- In PA, for example, it would seem that an MIH program could proceed under a "physician delegation" model under the Medical Practice Act…
- …or – could establish a program within the confines of the EMS System Act

Legal Basis for MIH

- The legal basis for an MIH program depends entirely on the legal framework of each state

Legal Basis for MIH

- Requires a thorough assessment of laws and regulations relating to:
  - Physician practice and delegation
  - EMS scope of practice
  - Home health licensing and regulation
  - Laws, regs and policies regarding dispatch

Pay Practice Issues

- Huge increase in litigation involving unlawful pay practices:
  - Misclassifying as "exempt" from OT
  - Improper OT calculations
  - Improper application of travel, sleep, and meal time rules
  - Misclassification as "independent contractors"

General Rule

- "Hours worked" includes:
  - All time when employee is required to be on duty, whether at the premises or a prescribed workplace
  - All time when an employee is *permitted* to work, whether or not actually required to do so

Overtime Issues

- General Rule: Overtime must be paid for hours worked over 40 in a seven day designated workweek unless the employee is "exempt" from the payment of overtime

"White Collar" Exemptions
29 CFR Part 541

- Executive
- Administrative
- Professional
  - Primary duty of performing work: "requiring advance knowledge in a field or science or learning that is customarily acquired by a prolonged course of specialized intellectual instruction, AND that is predominantly intellectual in character and includes work requiring the consistent exercise of discretion and judgment

Wage and Hour Issues

- Exempt from Overtime?
  - No, generally do not fit within any of the "white collar" exemptions from overtime
- Method of Payment
  - Hourly rate vs. "Per Visit" flat fee
    - Either method acceptable, but the total fee divided by the hours worked must exceed minimum wage and OT is still required for hours worked over 40 in the defined workweek

Travel Time

- Travel time compensable?
  - Generally, travel time between visits is compensable

Travel Time

- Employee's regular and daily commute is "ordinary home-to-work travel" - not compensable as work time
- BUT, if employee is required to report to a meeting place to receive instructions, pick up equipment, the travel from meeting place to work site is compensable
  - 29 CFR § 785.38

Home to First Work Site

- Employees must be compensated for time spent traveling from the place of performance of one principal employment activity to the place of performance of another principal employment activity
  - 29 CFR Sec. 790.7

Example

- Community Paramedic Pauline has 4 visits scheduled for tomorrow. She leaves from home and drives to the first visit and from there to the remaining 3 visits. The travel time from home to the first visit is NOT compensable but the travel time between those visits IS compensable

Use of Company Vehicle

- Otherwise non-compensable commute time is not compensable merely because employee commutes in a company vehicle, provided that:
  - Sites are within normal commuting area for the business
  - Use of vehicle subject to an agreement or mutual understanding – and restrictions on use of vehicle do not make commute time compensable

Example

- Community Paramedic Pauline takes a company car home to use the next day to do her visits. She is not allowed to use the vehicle for personal use and must keep her company issued cell phone on while using the vehicle. Her travel time to work is NOT compensable

Independent Contractor?

- Courts look to the "economic reality" of the relationship
  - Degree of control over employee
  - Investment of employee in tools and equipment
  - Employee opportunity for profit/loss
  - Skill and initiative required for the job
  - Permanency of the relationship
  - Extent work is an integral part of the employer's business

Independent Contractor?

- Bottom Line: Extremely difficult to prove that a Community Paramedic is an "independent contractor"
- Get good legal advice!