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27th Annual Health Law Forum
November 20, 2015

7:30 – 8:15 a.m. Registration and Continental Breakfast

8:15 – 8:30 a.m. Welcome and Introduction

Michael W. Chase

8:30 – 9:30 a.m. **A Tale of Snooping: Lessons Learned the Hard Way**

Inappropriate access to records or "snooping" remains one of the most significant risks for large and small health care entities. This session will explore the financial and reputational risks to your organization of snooping incidents as well as discuss the requirement for auditing employees' access to medical records to detect snooping. Vickie Ahlers will be joined by Anna Turman, Chief Operating Officer, Chief Information Officer of Chadron Community Hospital and Health Care Services, to discuss a real life snooping incident step by step from discovery to the Office for Civil Rights investigation that followed, and the lessons learned the hard way.

Vickie B. Ahlers
Anna Turman, COO, CIO | Chadron Community Hospital & Health Care Services

9:30 – 10:15 a.m. **Emergency Department Compliance; Telemedicine, Credentialing, EMTALA and Mid-Level Supervision**

Many critical access hospitals have benefitted from network and other tertiary hospitals' willingness to make emergency and mental health physicians available for consultation, particularly when the CAH ED is covered by a mid-level practitioner. Does this mean that the telemedicine physician is supervising the mid-level? Is the telemedicine physician "on-call" under EMTALA? Is any supervision required by a CAH Active Staff physician? And how thorough must credentialing be for the telemedicine physician? Whether or not relying upon telemedicine for mid-level supervision, must the supervising physician remain within any particular proximity of the CAH? Does it make a difference if the CAH has an obstetrical service, and only physicians are credentialed to perform deliveries? These arrangements clearly affect quality of care, and in many cases, the financial bottom line.

Barbara E. Person
Abigail T. Mohs, Law Clerk

10:15 – 10:30 a.m. Break

10:30 – 11:15 a.m. **Trending: Increased Reliance on Non-Physician Practitioners**

Increasingly, health care organizations are seeking non-physician practitioners (NPPs) such as nurse practitioners, physician assistants, and certified registered nurse anesthetists to fill the shortage of primary care and specialty physicians. Often times the NPPs (and the facilities, too) want the NPP to practice at the "top" of their license, with limited physician involvement. Or, they encounter physician resistance to use of these NPPs and seek to exclude them or severely limit their scope of practice. There are limitations and compliance concerns that follow the rise in NPPs, and Federal and State regulators are exercising increased scrutiny of NPPs. This session will focus on a number of compliance issues and recent policy changes (including the revised Nurse Practitioner Act in Nebraska under LB 107), supervision and collaboration requirements, medical staff credentialing and privileging, and scope of practice limits.

Alex M. (Kelly) Clarke
Michael W. Chase

11:15 a.m. – 12:00 p.m. **Physicians as New Focus of Stark/Anti-Kickback Liability**

A recent OIG Fraud Alert and several recent cases highlight the focus on physicians as the latest targets of Stark and Anti-Kickback prosecutions and *qui tam* actions. While there are a few older cases targeting physicians, the focus has primarily been on hospitals and other entities that received referrals from physicians. Now, that seems to be changing. This session will review the OIG Fraud Alert and a few recent cases and provide take-aways for compliance by physicians and the entities with whom they contract.

John R. Holdenried
Zachary J. Buxton

12:00 p.m. – 1:00 p.m.	Lunch
1:00 – 2:00 p.m.	**The Latest Word** This session includes the always popular, fast paced discussion of a variety of issues affecting health care organizations. This year's panel of Baird Holm attorneys will cover recent topics including technology issues, immigration updates, labor and employment issues, 340B, and several other health care compliance topics. *Panel of Baird Holm LLP Attorneys*
2:00 – 2:30 p.m.	**Health Care Investigations and Expert Opinions – They're Confidential...Right?** Health care organizations frequently conduct internal investigations and obtain expert opinions covering a myriad of topics, including coding and billing practices and fair market value. Many times these investigations and opinions contain sensitive information that may be harmful to the organization. Unfortunately, many organizations incorrectly assume that merely involving legal counsel protects investigative reports and expert opinions from discovery under the attorney-client privilege. This program will explore the "ins" and "outs" of the attorney-client privilege within a health care framework and suggest organizational best practices to preserve the attorney-client privilege. *Andrew D. Kloeckner*
2:30 – 2:45 p.m.	Break
2:45 – 3:45 p.m.	**Mentally Ill and Potentially Violent Patients: Legal Obligations and Practical Guidance** Severely disturbed, assaultive patients are making up an increasing proportion of patients brought to hospitals. Both acute care hospitals with behavioral health services/units and critical access hospitals are confronted with a wide range of issues in dealing with such patients. This session will cover topics including: permitted disclosures to law enforcement under HIPAA and other Federal and State law; emergency protective custody; Medicare Conditions of Participation governing patients' rights limiting use of force in clinical settings; payment for services for patients in legal custody; EMTALA requirements; admissions policies and obligations and coordination with resources in the broader community. *Julie A. Knutson*
3:45 p.m.	**Adjourn and Reception** *Please join us for complimentary cocktails and appetizers in the hotel lobby lounge.*

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27th annual HEALTH LAW FORUM

A Tale of Snooping: Lessons Learned the Hard Way

Vickie B. Ahlers

Anna Turman
COO and CIO,
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1700 Farnam Street, Suite 1500
Omaha, NE 68102
402.344.0500
www.bairdholm.com

A Tale of Snooping: Lessons Learned the Hard Way

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snoop
/snōōp/

informal

verb
gerund or present participle: **snooping**

investigate or look around furtively in an attempt to find out something, especially information about someone's private affairs.
"your sister might find the ring if she goes snooping around"
synonyms: pry into, inquire into/about, be inquisitive about/of, be curious about, poke about/around, be a busybody about, poke one's nose into; More

From OCR "Wall of Shame"

Breach Report Results

	Name of Covered Entity	State	Covered Entity Type	Individuals Affected	Breach Submission Date	Type of Breach	Location of Breached Information
	California Pacific Medical Center	CA	Healthcare Provider	845	01/23/2015	Unauthorized Access/Disclosure	Electronic Medical Record

Business Associate Present: No

Web Description: On or about October 15, 2014, during a routine review of workforce members' use of electronic protected health information (ePHI), the covered entity (CE), California Pacific Medical Center, discovered that a workforce member in the pharmacy department had impermissibly accessed the medical records of 13 coworkers. A subsequent audit showed that from October 2013 to October 2014, the workforce member had impermissibly used the medical records of a total of 845 individuals. The ePHI accessed included patient demographics, last four digits of social security numbers, clinical information about diagnoses, clinical notes, physician order information, laboratory and radiological data, and prescription information. OCR verified that the CE applied employee sanctions pursuant to its policy and procedure, provided breach notification to HHS, affected individuals, and the media, and retrained employees on relevant HIPAA policies and procedures.

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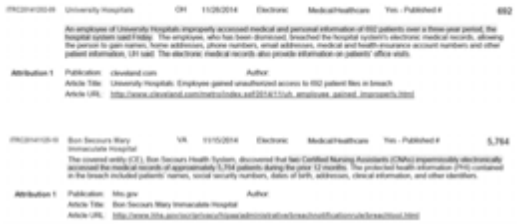
Snooping Data Breaches



Quiz: Forms of Snooping

- It's not snooping if it was "accidental"?
- It's not snooping if it was "innocent"?
- It's not snooping if it was "good intentioned"?
- It's not snooping if it was family or a friend?
- It's not snooping if it was "for educational purposes"?

"It Won't Happen Here"

- Many studies have found snooping still single most common occurrence of compromise to patient records
- If you think it isn't happening, you aren't looking hard enough
- Significant risk if you ignore the problem

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Snooping and the Privacy Rule

- Responsibility to protect from access by employee without job related reason requirement of the Privacy Rule
- Privacy Rule, 45 CFR §164.530(c):
  - Standard: "*Covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of PHI*"
  - Implementation Specification: "*A covered entity must reasonably safeguard PHI from any intentional or unintentional use or disclosure"*

Snooping and the Security Rule

- Requirement to look for snooping is part of Security Rule
- Security Rule, 45 CFR§164.308(a)(1)(ii)(D) &§164.312(b):
  - *"Information system activity review. Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports."*
  - "*Audit Controls. Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use ePHI."*

Snooping and Auditing Access

- Why Audit?
  - Detect inappropriate access, use or disclosure of PHI (ongoing monitoring of potential breaches)
  - Hold individuals accountable
  - Accreditation standards (Joint Commission)
  - Pattern of noncompliance (by an individual workforce member, department, etc.)
  - Detect issue before it becomes widespread

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Snooping and Auditing Access

- Targeted Audits
  - Did a patient complain? (Did a co-worker report?)
  - High profile patient?
  - User logged-on in more than one location?
  - Is a user on vacation or sick leave?
  - Accessing family or co-worker records?
  - Physicians accessing outside of their specialty?
  - Accessing records outside of department?

Lessons Learned at Chadron Community Hospital and Health Services

- CCH experienced a snooping incident by a CCH employee
- Investigation at time of incident was significant and time-intensive
- Notification to 482 patients

Lessons Learned at Chadron Community Hospital and Health Services

- Breach report to OCR was flagged for follow up investigation – even more time-intensive and expensive
  - 25 page response letter to OCR
  - 145 attachments based on OCR document request
- Based on thorough investigation and response by CCH, case closed by OCR without any further requirements
- What did we learn?

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Anatomy of a Snooping Investigation and Response

- Detection of possible incident
- Interviews(s)
- Auditing extent of possible snooping
- Sanctions
- Training
- New or revised policies
- Notification
- Documentation

Detection: Lessons Learned

- Fellow employee complaint (could also be patient complaint)
- Take it seriously (but be mindful of ulterior motives by employees or patients)
- Make sure employees understand obligation to report
- Make sure employees have avenue to express complaints/concerns
- Can you explain to OCR – why was this inappropriate access not identified previously? (Have you been auditing?)

Interviews: Lessons Learned

- Should conduct thorough interviews with:
  - Complaining employee (or patient if that is the case)
  - Other employees with potential for knowledge
  - Managers/supervisors of department knowledge of what access would be appropriate
  - Suspected snooping employee
- May need to repeat interviews after more information is learned
- Document interviews very thoroughly

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Auditing Extent of Snooping: Lessons Learned

Two toughest questions:

- How far back do you run your audit?
- How do you know what access was appropriate?

Auditing Extent of Snooping: Lessons Learned

- How far back do you run your audit?
  - Some factors to consider?
    - When was employee hired?
    - Any changes in job responsibilities?
    - Any changes in EHR or electronic record system?
    - Can you explain limitations in your system's audit capabilities? And your timeline/plan to remedy any limitation?

Auditing Extent of Snooping: Lessons Learned

- How do you know what access was appropriate?
  - Analysis of audit reports extremely time-intensive
  - What level of "proof" is required?
    - Proof to OCR that access was job-related?
    - Proof that access was not job-related if firing?
  - If no clear trail of job-related access, can you identify patterns or trends to suggest what access was business related and what was not?

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Sanctions: Lessons Learned

- Do you have a sanctions policy?
- Does sanctions policy give management flexibility to terminate?
- Zero-tolerance is trend but not absolute requirement under HIPAA

Training: Lessons Learned

- Can you provide documentation of training dating back six years?
- Can you prove each individual employee has received training (sign in sheet for in-person training or computerized documentation)?
- Make sure training clearly addresses snooping – dispel any myths!

Policies: Lessons Learned

- Do policies adequately address all required HIPAA requirements?
- Keep policies updated and retain all versions in effect for prior six years
- Are new or revised policies needed after incident?
  - Should review risk assessment and if snooping is not addressed as risk, include it
  - Revise any current policies that need revision
  - Implement new policies that could prevent the incident from being repeated
  - Train and document training on new policies

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Notification: Lessons Learned

- Letters to 482 patients
  - Multiple versions: minors, deceased, guardians
- Maintain proof of date of mailing
- Focus by OCR on undeliverable letters
  - If more than 10 are returned as undeliverable, requirement for media notice
  - Preamble to Breach Notification Rule suggests all remailings must happen within 60 day timeline (very difficult standard)

Documentation: Lessons Learned

- Important to maintain thorough documentation of entire process
- Timeline of events
- Incident report at conclusion – make your case at time of incident as if you will be required to defend actions to OCR
- OCR Document Request
  - Significant increase in documents requested from early days of enforcement

Documentation: Lessons Learned

1. A written, detailed description of the incident(s) described on the first page of this letter to include the date and method of discovery.
2. Please state whether you conducted an investigation concerning the incident(s) described on the first page of this letter. If so, please submit documents gathered during and related to the investigation as well as a copy of your findings.
3. Documentation supporting any claims that your facility responded to the incident(s) and mitigated, to the extent practical, the harmful effects of the incident.

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Documentation: Lessons Learned

4. A copy of the letter sent out notifying the affected individuals of the breach of their PHI, to include the date of mailing.
5. A copy of your log, or similar document, indicating the individual notifications that were returned as undeliverable.
6. A copy of CCH's policies and procedures for uses and disclosures of PHI.
   a. **Please submit all versions in effect from February 1, 2009, up to and including the present.**
   b. If a document does not state the date of implementation, please provide information related to its date of implementation.

Documentation: Lessons Learned

7. A copy of CCH's policies and procedures related to the minimum necessary requirements. See 45 CFR 164.502(b) and 164.514(d).
   a. Please submit all versions in effect from February 1, 2009, up to and including the present.
   b. If a document does not state the date of implementation, please provide information related to its date of implementation.
8. A copy of CCH's policies and procedures addressing how CCH administratively, technically, and physically safeguards patients' PHI.
   a. Please submit all versions in effect from February 1, 2009, up to and including the present.
   b. If a document does not state the date of implementation, please provide information related to its date of implementation.

Documentation: Lessons Learned

9. A copy of CCH's policies and procedures addressing how CCH administratively, technically, and physically safeguards patients' electronic PHI (ePHI).
   a. Please submit all versions in effect from February 1, 2009, up to and including the present.
   b. If a document does not state the date of implementation, please provide information related to its date of implementation.
10. Copies of all CCH's risk analyses, with corresponding dates, **in existence as of February 1, 2009, up to an including the present.** If a risk analysis does not state the date on which it was prepared, please provide information as to the date or period during which the risk analysis was performed.

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Documentation: Lessons Learned

11. Documentation evidencing CCH's security measures implemented to reduce risk and vulnerabilities identified through the above-noted risk analyses.
12. A copy of CCH's policies and procedures implemented to ensure the application of appropriate sanctions against HIPAA-noncompliant workforce members.
    a. Please submit all versions in effect from February 1, 2009, up to and including the present.
    b. If a document does not state the date of implementation, please provide information related to its date of implementation.

Documentation: Lessons Learned

13. Documentation evidencing that CCH's policies and procedures implemented to ensure application of appropriate sanctions against HIPAA-noncompliant workforce members are consistently applied.
14. A copy of CCH's policies and procedures pertaining to review of records of information system activity.
    a. Please submit all versions in effect from February 1, 2009, up to and including the present.
    b. If a document does not state the date of implementation, please provide information related toits date of implementation.

Documentation: Lessons Learned

15. Documentation evidencing that CCH's policies and procedures pertaining to review of records of information system activity are consistently applied.
16. A copy of CCH's policies and procedures implemented to ensure CCH's workforce has appropriate access to electronic protected health information (e-PHI) pursuant to §164.308(a)(3)(i), the Workforce Security Standard; e.g., Are the procedures used by your workforce consistent with your access policies (i.e., do people who should have access actually have that access? Are people who should not have access prevented from accessing the information?)
    a. Please submit all versions in effect from February 1, 2009, up to and including the present.
    b. If a document does not state the date of implementation, please provide information related to its date of implementation.

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Documentation: Lessons Learned

17. Documentation evidencing CCH's HIPAA-related workforce training, to include presentation materials, sign-in sheet(s) or other document(s) confirming workforce attendance and/or completion of training.
18. A copy of the March 7, 2014 patient complaint alleging that a member of the CCH's workforce impermissibly accessed the patient's PHI.

Documentation: Lessons Learned

19. A copy of the CCH's policies and procedures related to audit controls, and evidence that these policies were implemented.
    a. Please submit all versions in effect from February 1, 2009, up to and including the present.
    b. If a document does not state the date of implementation, please provide information related to its date of implementation.
20. Submission of any other information that would be useful to OCR in this investigation.

Questions?

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Thank You

Vickie B. Ahlers
(402) 636-8230
vahlers@bairdholm.com

Anna Turman
Chadron Community Hospital & Health Services
(308) 432-0289
coo@chadronhospital.com

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27th annual HEALTH LAW FORUM

Emergency Department Compliance; Telemedicine, Credentialing, EMTALA and Mid-Level Supervision

Barbara E. Person

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1700 Farnam Street, Suite 1500
Omaha, NE 68102
402.344.0500
www.bairdholm.com

Emergency Department Compliance; Telemedicine, Credentialing, EMTALA, and Mid-Level Supervision

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Hospitals and Practitioners Affected

- Critical Access Hospitals and their practitioners covering the ED, using/considering reliance on telemedicine support
- Larger hospitals whose staff physician(s) support EDs of CAHs and other community hospitals through telemedicine

Permissible CAH ED Staffing

- On-site 24/7 physicians
- On-site PA or NP with local physician on-call
- Off-site 1st call physician, PA or NP with local physician supervisor for PA or NP on 2nd call
- First call PA or NP with telemedicine consult and local physician supervisor on 2nd call
- PA or NP on-call with telemedicine physician and no local physician on call

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Regulatory Systems

- EMTALA
- CAH CoPs
- State Licensure Laws for supervision of PAs and NPs

CAH CoP Emergency Services

- An MD, DO, **PA, NP or CNS** with training or experience in emergency care must be immediately available by phone and available to be on-site within 30 minutes on a 24-hour a day basis
  - 42 CFR §485.618(d)(1)
- MD/DO not required to be available on-site when mid-level is on-call

CAH CoP Emergency Services

- MD or DO must be immediately available by phone or radio contact
  - 42 CFR § 485.618(e)
- This requirement can be met with the use of telemedicine
- This is different than the EMTALA on-call requirement

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Basic EMTALA Requirements

- Medical Screening Exam
  - Can be performed by non-physician practitioner, as identified by governing board
  - Telemedicine physician can assist or direct the examination
- Stabilizing treatment OR appropriate transfer for those identified through the screening to have an emergency medical condition

EMTALA Requirements for Physician Involvement

- These limit independence of PAs and NPs covering a CAH ED:
  - Physician on-call List:
    - Generally expected that physicians are on secondary call to mid-levels' primary call
    - Physicians are responsible for acts of the mid-levels
    - Only physicians are subject to EMTALA sanctions, not mid-levels

EMTALA Requirements for Physician Involvement (cont.)

- These limit independence of PAs and NPs covering a CAH ED:
  - Physician Certification of Transfer
    - that benefits outweigh risks
  - Prior to transfer, mid-levels must have a physician agree to countersign the certification, if a physician is not present in the ED

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EMTALA On-Call Requirements

- CMS Interpretive Guidelines
  - On-call list must be MDs or DOs
  - Non-physician practitioners do not satisfy this requirement
  - On-call physician must be available to make an in-person appearance at the hospital within a reasonable amount of time, or he/she may be subject to financial penalties
- BUT . . . 2013 CMS S&C Letter implies that 24/7 physician on-call coverage is not required

EMTALA On-Call Requirements

- 2013 CMS S&C Letter:
  - A CAH with only a few local physicians is not required to have one of them on-call 24/7
  - There is no requirement for all physicians holding CAH privileges to take call
  - No requirement for CAH to include a telemedicine physician providing emergency consultation on its on-call list
  - However, CAH must meet community needs consistent with local human resources

Hospital Credentialing/Privileges of Telemedicine Providers

- Telemedicine physician (or local physician) may certify transfer (that the benefits outweigh the risks)
  - This requires some level of privileging
- Credentialing may become burdensome depending on the number of physicians used for telemedicine support

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Licensure of Telemedicine Providers

- Licensure laws require the physician to be licensed in the state where the patient is treated
- Limit telemedicine doctors to physicians licensed in the state where the CAH is located

Patient Care in the CAH ED

- When a telemedicine physician is involved in treatment of a CAH ED patient, there is no requirement that a local on-call physician be available to be on-site
- So, if the necessary patient care is beyond the abilities of the mid-level, and no local physician is on secondary call, what next?

No Local Physician On-Call

- The CAH can request a local physician who is not on-call to come in and stabilize the patient; or
- The CAH may transfer the patient to another hospital for stabilization, following the EMTALA rules for "appropriate transfer"

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CAH CoPs

- Physician must be advised of each admission by a PA or NP 42 CFR 485.634(c)(3)
  - Telemedicine physicians don't have admitting privileges
- Physician must review a portion of outpatient records and all inpatient records created by PAs and NPs

Physician Supervision of Midlevels & Telemedicine

- How does the use of a telemedicine provider impact the state supervision requirements of midlevel practitioners?
- IA and NE laws vary significantly
- If contemporaneous supervision required, can telemedicine physician do it?

Nebraska Supervision Requirements: PAs

1. In order to supervise a Nebraska-licensed PA, a physician must hold a Nebraska license to practice medicine.
2. A supervising physician must maintain a written and executed supervisory agreement with each PA he supervises, defining the scope of practice of the PA and stating that the supervising physician will retain professional and legal responsibility for medical services rendered by the PA.

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Nebraska Supervision Requirements: PAs

3. The supervising physician must maintain a copy of the supervisory agreement on file at his primary practice site as well as at the practice site where the PA provides medical services.
4. A licensed physician may supervise no more than four PAs at a time, unless a waiver is granted.

Nebraska Supervision Requirements: PAs

5. The supervising physician bears strict liability for any negligent act or omission by the PA.
6. Together, the PA and supervising physician are responsible to ensure that the delegation of medical tasks is appropriate to the PA's competence, the relationship of and access to the supervising physician is defined, and a process for evaluation of the performance of the PA is established.

Nebraska Supervision Requirements: PAs

7. If the PA has less than two years of experience and provides medical services in a setting geographically remote from the supervising physician, the supervising physician must review a minimum of 20 patient medical records per month.
8. Supervision of the PA must be continuous, but does not require the physical presence of the supervising physician at the time and place that the services are rendered.

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Nebraska Supervision Requirements: PAs

9. The medical services delegated to the PA for a component of the supervising physician's scope of practice.
10. In order for a PA to practice in a hospital, the supervising physician must be a member of the hospital's medical staff.

Nebraska Supervision Requirements: NPs

- No supervision requirements after 2,000 clinical hours (08/30/2015)
- NPs with less than 2000 clinical hours must have a Transition-to-Practice agreement
  - The agreement must be with a supervising provider (MD, DO, NP) licensed in the state in the same or related practice specialty

Iowa Supervision Requirements: PAs

1. A PA must be supervised by one or more physicians; but a physician must not supervise more than five PAs at the same time.
2. The supervising physician must review the PA's patient care on an ongoing basis, which does not necessarily mean reviewing every chart or being physically present for every activity.

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Iowa Supervision Requirements: PAs

3. Patient care provided by the PA may be reviewed by the supervising physician in person or by telecommunicative means.
4. When signatures are required, electronic signatures are allowed under 2 conditions
   - The signature is transcribed by the signer, and
   - It is verifiable.

Iowa Supervision Requirements: PAs

5. Training of new medical procedures must be done under the supervision of the supervising physician. The PA may perform the new medical procedures when the supervising physician determines the PA is competent to perform the task.

Iowa Supervision Requirements: NPs

- It is recommended that NPs establish a professional relationship with physicians to ensure patients receive quality health care

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In short…

- CAH may staff mid-levels for first response to emergency care
- EMTALA requirements allow joint effort of a midlevel in the ED, a telemedicine physician, and a local physician
  - The local physician may be scheduled on-call (available to come on-site) but need not be
- PA supervision requirements that must be followed if a PA is staffing a CAH ED
- NP supervision is far less rigorous

To-Do List for CAHs Using Telemedicine in ED

- Consider whether available resources and community needs require local physician on-call, in addition to telemedicine physician
- Ensure that physician supervision requirements are met, either through local physician or telemedicine physician

To-Do List for CAHs Using Telemedicine in ED

- Ensure that telemedicine physicians are credentialed to do all functions required of them for EMTALA-compliance (certification and transfer order)
- Ensure that ED admissions result in notification of a physician – documented

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To-Do List for CAHs Using Telemedicine in ED

- If local physicians will not be on-call 24/7, this should be addressed in the on-call policy
  - Explanation as to why this is safe
  - Plan for emergencies exceeding capabilities of mid-level practitioner

Questions?

Thank You

Barbara E. Person
(402) 636-8224
bperson@bairdholm.com

Abigail T. Mohs
(402) 636-8296
amohs@bairdholm.com

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Trending: Increased Reliance on Non-Physician Practitioners

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Trending: Increased Reliance on Non-Physician Practitioners

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Michael W. Chase

Agenda

- Licensure developments in Nebraska
- Virtual office visits
- Medical staff/credentialing issues
- Payor and compliance issues
- Stark Law – midlevel recruitment exception

Nurse Practitioners – LB 107

- Removes statutory requirement for integrated practice agreement
  - Submit "transition-to-practice agreement" or evidence of 2,000 hours of practice under a transition-to-practice agreement, a collaborative agreement, integrated practice agreement, through independent practice, or a combination

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Nurse Practitioners – LB 107

- Acute CoPs: quality assurance/performance improvement program
- CAH CoPs: QA/PI; physician review of all inpatient and a sample of outpatient records
- RHC CFCs: periodic physician review of patients cared for by NPs

Nurse Practitioners – LB 107

- Professional interaction between employed NPs and physicians will continue
- Physicians and NPs desire meaningful and effective collaborative and consulting relationship
- Discuss LB 107 issues and legal standards with physicians and medical staff

Nurse Practitioners – LB 107

- Have a written agreement with NP and a physician member of the medical staff
  - If less than 2,000 hours: supervision and then collaboration (agmt automatically moves to collaboration)
  - If more than 2,000 hours: collaboration
- Update medical staff bylaws, rules and regulations, policies, forms, etc.

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Midlevels and Virtual Visits

- Internet-based clinics for minor illnesses and injuries
- Access by computer, tablet or smartphone
- Existing and new patients
- Some providers tie log-in ability to geographical location

Midlevels and Virtual Visits

- Could lead to treating patients in more than one state
- Requires midlevel to have multiple state licenses
- RN Licensure Compact does not extend to midlevel practitioners

Midlevels and "Incident to" Billing

- Physicians, PAs, Clinical Psychologists, NPs, CNSs and CNMs can bill "incident to"
- Services are integral though incidental part of the practitioner's services
- Require "direct supervision"
- Billed as if performed by billing physician

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Midlevels and "Incident to" Billing

- CMS to amend the rule
- Can only be billed by practitioner who supervises the procedure
- No longer the ordering practitioner or treating practitioner unless also the supervising practitioner
- *"Practitioner is stating that he or she performed the service or directly supervised the auxiliary personnel performing the service"*

Midlevels and "Incident to" Billing

- Implications for practices where patients undergo a series of treatments and supervising physician is not the treating physician (*i.e.,* oncology)
- Implications under Stark-group practice productivity credit

Credentialing Issues

- Governing body determines which practitioners are eligible for medical staff appointment
- Subject to nondiscrimination laws
- Medical staff determines the duties and scope of privileges
- Not every NPP can perform every privilege listed in the NPP's category

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Credentialing Issues

- Nebraska: PAs
  - Derivative provider
- Nebraska: NPs
  - Independent provider
- Nebraska: CNMs
  - Independent provider
  - High risk area and require practitioner relationship
- Physician role and "privileges"

Credentialing Issues

- Iowa PAs
  - Derivative provider
- Iowa NPs
  - Independent provider
- Iowa CNMs
  - "Non-status"
- Physician role and "privileges"

Midlevel Recruitment

- Physician recruitment exception
  - Does not require *quid pro quo*
  - Purpose is to recruit physician to serve community
  - Not intended to confer a benefit on the physician practice
  - Inapplicable to recruiting midlevels to community

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Midlevel Recruitment

- (New) Final Stark exception to support midlevel recruitment and hires by physicians
- Eligible Participants
  - Hospitals
  - RHCs
  - FQHCs
- Eligible Practitioners
  - NPs
  - CNS
  - PAs
  - Clinical psych
  - CSWs
  - CNMs
- Must become W-2 employee of physician

Midlevel Recruitment

- *Substantially all* primary care services or mental health services
- No practice restrictions on midlevel preventing them from providing services
- Lower of 50% of salary and benefits or salary and benefits less collections
- Max 2-year payments

Midlevel Recruitment

- Three-party contract
- Referral, volume and value restriction
- Advice
  - Obtain, vet, hold physician to the employment agreement, job description
  - Condition ongoing payment on compliance

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Questions?

Thank You

Alex M. (Kelly) Clarke
(402) 636-8204
aclarke@bairdholm.com

Michael W. Chase
(402) 636-8326
mchase@bairdholm.com

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27th annual HEALTH LAW FORUM

Physicians as New Focus of Stark/ Anti-Kickback Liability

John R. Holdenried

Zachary J. Buxton

BAIRD HOLM LLP
ATTORNEYS AT LAW
EST. 1873

1700 Farnam Street, Suite 1500
Omaha, NE 68102
402.344.0500
www.bairdholm.com

Physicians as New Focus of Stark/Anti-Kickback Liability

John R. Holdenried
Zachary J. Buxton

Baker and Its Progeny

- Baker (Houston radiologist) owns imaging center
- Alleged to pay illegal compensation to referring physicians
  - Sham medical directorships
  - Placed referral coordinators in physician offices who then performed office functions
- *Qui tam* – brought by 2 physicians who used imaging services

Baker and Its Progeny

- Baker settled for $650,000 and 6-year exclusion in 2012
- OIG then pursued physician recipients
- 11 physicians have settled (total $1.4 million)
- 1 physician excluded

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#	Physician Name	Practice Area	Settlement Date	Settlement Amount	Compensation Arrangement
1	Unknown Physician #1	Family Practice	4/24/2014	Exclusion (3 years)	Medical Director
2	Mary Campbell-Fox	Family Practice	1/6/2014	$195,016.00	Medical Director/referral coordinator
3	Amir Ghebranious	Family Practice	1/6/2014	$195,016.00	Medical Director/referral coordinator
4	Victor Van Phan	Orthopedist	8/28/2013	$188,000.00	Medical Director
5	Gary Stephen Hurwitz	Urologist	8/11/2014	$170,000.00	Medical Director
6	Dilipkumar Chotabhai Patel	Family Practice	8/11/2014	$146,000.00	Medical Director
7	Jerry McShane	Occupational Health	6/26/2014	$134,200.00	Medical Director/referral coordinator
8	Steven A. Fein	Gastroenterologist	6/26/2014	$118,944.00	Medical Director/referral coordinator
9	Robert L. Burke	Orthopedic Surgeon	10/2/2014	$99,000.00	Medical Director
10	Thanh A. Nguyen	Urologist	9/9/2014	$60,000.00	Medical Director
11	Dan Kelly Eidman	Orthopedic Surgeon	10/17/2014	$50,000.00	Medical Director
12	Jimmy Dung Doan	Family Practice	10/17/2014	$50,000.00	Referral coordinator

Average Settlement (per physician) **$127,834.18**

OIG Fraud Alert – Physician Compensation Arrangements

- Released June 9, 2015
- Describes recent settlements with 12 physicians receiving improper compensation in Baker case
- Concludes the physicians were "an integral part of the scheme"
- Physicians must ensure that payments are FMV for *bona fide* services they actually provide
- Arrangements that relieve physicians of a financial burden are also improper remuneration

OIG Fraud Alert – Physician Compensation Arrangements.)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability

June 9, 2015

Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide. Although many compensation arrangements are legitimate, a compensation

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"[The] OIG encourages **physicians** to carefully consider the terms and conditions of **medical directorships** and other compensation arrangements **before entering into them**."

Columbus Regional Health

Ledger-Enquirer

HEALTH CARE

Columbus Regional to pay up to $35 million to end whistleblower lawsuit

Ledger-Enquirer

LOCAL

Unsealed: Top administrator at Amos Cancer Center files federal court claim accusing the center of overbilling government insurers

Columbus Regional reaches $35M settlement with the state of GA

Columbus Regional Background

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Columbus Regional Background

- Columbus, Georgia
- Established 1986, nonprofit
- Hospital system
  - Three hospital system
- Service area: 189,885 residents
  - 10 counties

Columbus Regional Background

- *Qui tam* filed by former administrative director of Cancer Center
- Alleged – oncologists paid stipends for medical director services
- Pippas received clinical comp based on work of other physicians and mid-levels and upcoding

Columbus Regional Settlement

- Unsealed June 2013, settled September 2015
- Settlements from health system & physician
  - Columbus Regional: $26,000,000
  - Dr. Andrew Pippas: $425,000
  - Legal Fees: $10,000,000

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Barker v. Tidwell

- *Qui tam*
- Tidwell sold radiation oncology clinic to Columbus, Georgia hospital
- Alleged payment in excess of FMV to induce Tidwell to make referrals
- Alleged FCA liability for billings following sale of physician cancer center to hospital
- Brought against physician owner and hospital buyer
- Alleged sale price exceeded FMV

Barker v. Tidwell

- Court: No summary judgment; if the jury concluded that he believed that the Treatment Center was worth less than what he received based on other evidence, including a valuation firm's "high end" value that was $500,000 below the purchase price, the jury would be authorized to conclude that the amount paid in excess of fair market value was a kickback for referrals
- Case recently dismissed (settlement not disclosed)

A Plus Home Health Care

- Home health agency in south Florida
- Alleged: hired 7 physician spouses and one boyfriend to perform sham marketing duties
- Alleged: 2 spouses fired when husbands didn't make required referrals
- *Qui tam*—brought by former director of development of A Plus

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A Plus Home Health Care

- HHA and its owners settled for $1.65 million
- Separate settlements with 5 of the couples (prior to HHA settlement)

"The Yates Memo".)

"The Yates Memo".)

- Released September 9, 2015
- Increased focus on <u>individuals</u> responsible for corporate wrongdoing
  - Corporations act "through individuals"
- Six "key steps"
  - DOJ's plan to address corporate wrongdoing by focusing on individual culpability

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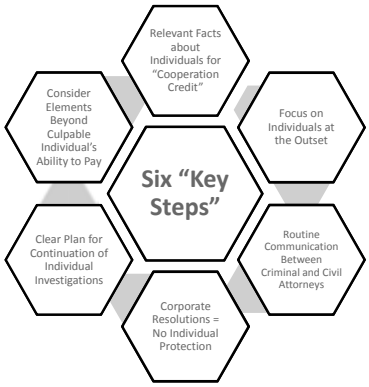

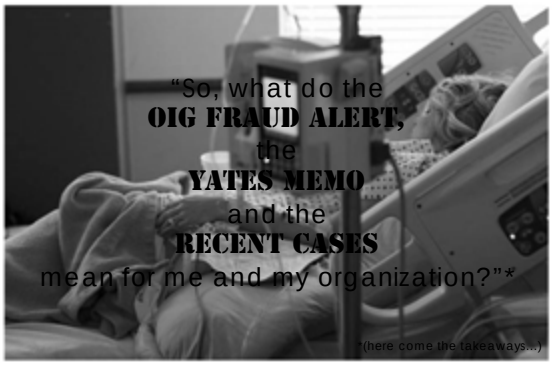

Takeaways

- It's *qui tam*, not government investigation
- Respond to concerns
- If it's not appropriate without referrals, it's not appropriate
- Wild West days for physicians are over
- Focus on physicians who receive benefits as well as executives responsible

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Takeaways

- Physicians should be just as concerned about documentation of FMV and commercial reasonableness as hospital
- "Never Statements"

Questions?

Thank You

John R. Holdenried
(402) 636-8201
jholdenried@bairdholm.com

Zachary J. Buxton
(402) 636-8239
zbuxton@bairdholm.com

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The Latest Word

Panel of Baird Holm LLP Attorneys

BAIRD HOLM LLP
ATTORNEYS AT LAW
EST. 1873

1700 Farnam Street, Suite 1500
Omaha, NE 68102
402.344.0500
www.bairdholm.com

The Latest Word

Panel of
Baird Holm LLP Attorneys

Site-Neutral Medicare Payments

Julie A. Knutson

Site-Neutral Medicare Payments Bi-partisan Budget Act of 2015

- Section 603 proposes that, effective January 1, 2017, Medicare payments for most items and services furnished in an off-campus department of a hospital would be paid under the applicable non-hospital system – MPFS or ASC fee schedule

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Site-Neutral Medicare Payments Bi-partisan Budget Act of 2015

- Does NOT apply to:
  - Locations billing as a department of a hospital (provider-based) prior to the date of enactment
  - Off-campus emergency services coded under HCPCS Codes 99281-99285

Thank you

Julie A. Knutson

Overpayments—60 Day Rule

Zachary J. Buxton

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60-Day Overpayment Rule

- ACA: the latter of
  - 60 days after date the overpayment was identified; or
  - The due date of a corresponding cost report
- Many in the industry take the position that, as long as provider diligently pursues quantification, then no known overpayment pending results of those efforts

7

60-Day Overpayment Rule

- *Kane v Continuum Health Partners, Inc. et.al.*
- NY hospitals had software glitch; received Medicaid overpayments
- State auditor notified hospitals
- Internal audit inquiry; Kane sent analysis/spreadsheet to management
- Kane terminated; hospital did nothing further
- Civil Investigative Demand (1 year later); hospital repaid

8

60-Day Overpayment Rule

- *Kane* Court:
  - Internal assessment delivered to management – 60-day requirement was triggered
  - Rejected argument that "identified" means "conclusively proven to be an overpayment"
  - Court did leave some room for subjective analysis
- Lesson: investigative potential overpayments quickly and thoroughly

9

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Thank you

Zachary J. Buxton

Immigration Update

Amy Erlbacher-Anderson

Conrad 30 Program

- Each state has 30 waivers to grant to foreign physicians – up to 10 for non-shortage areas
- Physician must work for healthcare facility for a minimum of 3 years
- Currently authorized until December

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Reform

- Increases available waivers if 90% are used nationwide
- Extensions for physicians denied waivers due to state reaching quota
- Makes Program permanent
- Expands exemptions from visa caps

Thank you

Amy Erlbacher-Anderson

Labor & Employment Update

Scott S. Moore

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Labor & Employment Update

- Quickie elections / action plan
- NLRB Gone Wild / Handbook Reviews
- Affirmative Action
- Wage and Hour Audits
- Exemption Salaries
- Wellness Plan Rules

Thank you

Scott S. Moore

340B Mega-Guidance

Barbara E. Person

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340B Mega-Guidance

- Could significantly decrease volume of drugs that could be purchased through 340B
  - Prescriptions written in unregistered sites would be excluded
  - Guidance would disqualify (a) hospital discharge prescriptions, (b) infusions ordered outside hospital and (c) pre-admission drugs for PPS hospitals
  - Drugs paid for by Medicaid in a bundled manner would be disqualified
  - Medicaid MCO drugs dispensed by contract pharmacies would be "presumed" to be carved out

340B Mega-Guidance

- Significantly increased admin. burden
  - Elimination of materiality standard for self-disclosures
  - Patient definition would require satisfying six tests rather than three
    - Biggest change is requirement that ordering provider be employed or contracted by Covered Entity so as to support billing for professional services by CE
- Unclear from Guidance what is current policy and what is proposed

Thank you

Barbara E. Person

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Meaningful Use Final Rules

Abigail T. Mohs

Meaningful Use Final Rules

- Stage 2 modifications
- Common set of objectives
- 2015 (90-day reporting period)
  - Tied to calendar year
  - 1 patient uses patient portal (EHs, CAHs, EPs)
  - Secure messaging enabled (EPs)
- 2016 – 2017
  - Full calendar year

Meaningful Use Final Rules

- Stage 3
  - Officially begins in 2018 (but providers may start early in 2017)
  - Increased patient engagement
    - Access through APIs (i.e., mobile apps)
    - Integration from non-clinical settings (i.e. Fitbit)
  - Continue to prepare/plan for ongoing implementation

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Thank you

Abigail T. Mohs

Free Texting/Mobile Order Applications

Michael W. Chase

Free Texting/Ordering Apps

- Privacy and security issues
  - Texts and orders contain PHI
  - Theft (about 56%) and loss of mobile devices are primary reason for breaches >500
  - Is the data encrypted?
  - Compliance issues
  - Documentation in the medical record

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Free Texting/Ordering Apps

- Password/passcode protection
- Encryption (data at rest and in-transit)
- Mobile Device Management
  - For both organizationally-owned and personally-owned mobile devices for Bring Your Own Device (BYOD)
- Mobile device policy and user agreement
- Process for documenting in medical record

Thank you

Michael W. Chase

Nebraska Governmental Hospital Foundations

Andrew D. Kloeckner

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Frederick v. City of Falls City

- Are quasi- or "hybrid" governmental/private entities subject to Nebraska Open Meetings and Public Records laws?
- Nebraska Supreme Court adopted a 4 Factor Test:
  - Whether private entity performs a governmental function
  - The level of government funding
  - Extent of government involvement/regulation
  - Whether the entity was created by the government
- Case-by-case basis
- No factor is dispositive

Neb. AG Opinion #15-016

- MECA subject to open meetings and public records laws
- Analysis of *Frederick* factors:
  - Operating city buildings is an essential function of city government
  - 75% of initial funding through bond issuance; ongoing city budgetary allocations
  - All board members appointed by city council/mayor
  - Powers and duties of MECA set forth in city ordinance; *ex officio* role of city officials (treasurer); city audit; office location in city buildings
  - Even though initially created by private individuals, city ordinance/public vote "created" MECA

Thank you

Andrew D. Kloeckner

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Health Care Investigations and Expert Opinions– They're Confidential...Right?

Andrew D. Kloeckner

BAIRD HOLM LLP
ATTORNEYS AT LAW
EST. 1873

1700 Farnam Street, Suite 1500
Omaha, NE 68102
402.344.0500
www.bairdholm.com

Health Care Investigations and Expert Opinions–They're Confidential...Right?

Andrew D. Kloeckner

Common Myths

- "As long as I include my lawyer in the e-mail chain, it's a protected communication"
- "As long as my lawyer engages or reviews a third-party audit, it will be protected"
- "All my communications with in-house counsel are protected"

Attorney-Client Privilege

- Protects communications between a client and lawyer when the purpose of the communication is to seek legal advice
- Encourages open and complete communication by eliminating possibility of compelled disclosure

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Attorney-Client Privilege

- Is there a communication?
- Is the communication made in confidence?
- Is the communication made to or by an attorney (or subordinate acting on behalf of the attorney)?
- Does the communication relate to the representation?
- Has the privilege been waived?

Attorney-Client Privilege

- In-house counsel – Purpose and intent test
  - Generally heightened scrutiny
  - Is the purpose and intent of a communication to relay legal advice?
    - General business advice not protected
  - What is the ***primary*** purpose?
  - Is the matter within the scope of employment?

Work Product Doctrine

- Separate from attorney-client privilege
- Protects documents and materials prepared by a party in anticipation of litigation
- Expands beyond communications

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Baklid-Kunz v. Halifax

- *Qui tam* action alleging violation of FCA under the Stark law
- Questions regarding FMV of certain physician compensation arrangements
- Relator was hospital compliance officer
- Hospital in-house counsel says arrangements violate Stark
- Second opinion from outside law firm – "reasonable argument" of Stark compliance

Baklid-Kunz v. Halifax

- Documents/communications at issue
  - Compliance logs
  - Communications with internal legal counsel
  - Documents created by hospital related to compliance reviews/audits
  - Documents stamped "confidential attorney-client privilege" or "attorney-client work product"
  - Documents related to FMV determinations and analysis

Baklid-Kunz v. Halifax

- No lawyers listed on privilege log communications
- Communications between non-lawyers:
  - Not reflective of legal advice previously given by lawyers
  - Not prepared for transmission to legal counsel or to be used in the provision of legal advice

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Baklid-Kunz v. Halifax

- Even when attorneys involved, not conveying legal advice
  - Primary purpose must be to seek or provide legal advice
- Corporate structure irrelevant – compliance department reports to legal department
  - Compliance advice ≠ legal advice

Kellogg, Brown & Root Litigation

- Non-health care FCA case
  - More famous for declining to extend WLSA tolling provisions to civil FCA claims
- Significant battle over privilege in internal investigations
- Federal District Court ruled investigative files related to fraud allegations must be turned over
- U.S. Court of Appeals overturned

Kellogg, Brown & Root Litigation

- District Court
  - Waiver of privilege because KBR put contents of its investigation at issue
    - Presented testimony/deposition of in-house lawyer in connection with motion for summary judgment
  - Investigative reports prepared by non-lawyers not privileged

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Kellogg, Brown & Root Litigation

- Court of Appeals
  - Designating an in-house lawyer to serve as the deponent does not waive the privilege
    - Privilege must continue to be asserted
  - That an internal investigation took place was not key to the claim
  - KBR investigators stepping in the shoes of lawyers
    - Investigators putting information in a usable format
    - Declined to extend protection to ***all*** investigative reports

Key Take Aways

- Attorney-client privilege not guaranteed; courts narrowly construe privileges
  - Fact intensive analysis
  - Different courts can make different determinations
- Marking something "attorney-client privileged" does not make it attorney-client privileged

Key Take Aways

- Privilege logs and descriptions of investigations should describe basis for attorney-client privilege
- Copying attorneys does not protect the communication
- Legal advice must be sought and must be the primary purpose of the communication

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Key Take Aways

- Each e-mail in a chains is analyzed separately for privilege purposes
- Subsequent communications of protected legal advice must be limited to those who need to know ***and*** be for the purpose of communicating the legal advice

Best Practices

- Establish and maintain direction of internal investigations by attorneys
  - Documents generated by non-lawyers should indicate creation at direction of counsel
- Consider using outside counsel
  - Courts tend to favor finding privilege when outside counsel is involved as opposed to solely in-house counsel

Best Practices

- Consultants
  - Lawyers (not providers) should engage third-party experts to provide opinions/reviews
    - Should be for purpose of guiding the lawyer in providing legal advice
  - Reports/findings should go through and be vetted by legal counsel prior to review by provider
  - Retrospective vs. concurrent reviews

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Best Practices

- Where possible/practical, call instead of e-mail
- Address communication to the lawyer; not "cc"
- Include privilege clause in subject line
- Include language requesting "legal advice"
- Do not combine business questions with legal questions

Best Practices

- Do not include legal advice in "chain e-mails"; include only those who need to know
- Do not forward legal advice and create a "chain e-mail"

Questions?

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Thank You

Andrew D. Kloeckner
(402) 636-8222
akloeckner@bairdholm.com

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Mentally Ill and Potentially Violent Patients: Legal Obligations and Practical Guidance

Julie A. Knutson

BAIRD HOLM LLP
ATTORNEYS AT LAW
EST. 1873

1700 Farnam Street, Suite 1500
Omaha, NE 68102
402.344.0500
www.bairdholm.com

Mentally Ill and Potentially Violent Patients: Legal Obligations and Practical Guidance

Julie A. Knutson

Introduction/Background

- Insufficient mental health resources have resulted in increased numbers of severely mentally ill and potentially violent individuals presenting to hospital EDs

Background

- All parts of the system are stressed
  - EDs
  - Hospitals with and without BHUs
  - Law enforcement agencies
  - County attorneys
  - Public institutions
  - Correctional facilities

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Background

- Often the most seriously mentally ill persons cannot immediately be placed anywhere due to extreme behavior
- Inappropriate incarceration may result

Background

- Various statutes and regulations impose requirements or limit hospitals in responding to this category of patients
- We'll consider several common situations illustrating these issues

Scenario #1

- An individual is brought to a CAH Emergency Department for evaluation under emergency protective custody; the patient is aggressive and threatening, requiring two law enforcement officers to manage him, although he is in handcuffs

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Scenario #1

- The hospital does not have a BHU
- The hospital does not have a psychiatrist on staff or on call
- The officers want to leave the patient in the ED but offer to leave the handcuffs on the patient until he calms down
- The patient has no physical injuries or medical conditions

What to do? Which rules apply?

- EMTALA; the hospital must:
  - Provide MSE within its capabilities to determine whether there is an EMC
  - Stabilize for transfer, if possible
  - Physician certification of the risks and benefits of transfer if unstable transfer
  - Arrange for a proper method of transfer in light of patient's condition and risks

Conditions of Participation/Handcuffs as Restraint

- The acute hospital CoPs, which clearly prohibit the use of law enforcement restraints – handcuffs – by hospital staff have not been made applicable to CAHs by CMS except for swing beds

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Easier Said Than Done

- Persuade officers to remain with patient until chemical restraints can be administered
- Arrange for a psychiatric consult or an appropriate transfer

What About States' Hospital Licensure Rules?

- Iowa regulations (481 IAC 51.6) governing patients' rights require development of a statement of principles about patient rights/responsibilities–no specific reference to restraints

- Nebraska regulations (175 AC 9-006.04) state that patient rights include the right to "be free from chemical and physical restraints that are unnecessary"
- Common sense answer?
- Many CAHs have opted for procedures similar to acute hospital CoPs

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Scenario #2

- Law enforcement officers bring a woman to an acute care hospital ED because she has expressed suicidal intent; the patient is under arrest and in custody in the county jail
  - The patient is cooperative and is willing to admit herself voluntarily to the hospital's BHU
  - Before leaving, the officers explain that the patient has been "unarrested," would like a call when she is ready to be released

Can the Hospital Do This?

- HIPAA only permits disclosures to law enforcement officers under very limited circumstances; this is not one of them

HIPAA: Disclosures of Protected Health Information (PHI) to Law Enforcement

- In general, disclosure under subparagraph 512(f) is allowed only:
  - For a law enforcement purpose, and
  - To a law enforcement official

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HIPAA: Disclosures of PHI to Law Enforcement

- Six Factual Scenarios
  - Set out in 45 CFR § 164.512(f)(1) – (f)(6)
  - All stated conditions must be met in support of disclosure

- (f)(1) Pursuant to process and as otherwise required by law
  - "Wounds of violence" statutes, or
  - In compliance with:
    - A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer; or
    - A grand jury subpoena; or
    - Administrative or investigative demand

- (f)(2) Limited information for identification and location purposes
  - Except for disclosures required by law as permitted in (f)(1), "a covered entity may disclose PHI *in response to a law enforcement official's request* for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person
    - No DNA
    - No analysis of body fluids or tissue
    - No dental records

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- (f)(3) Victims of a Crime
  - Except for disclosures required by law as permitted in (f)(1), "a covered entity may disclose PHI in response to a law enforcement official's request for such information about an individual who is not suspected to be a victim of a crime

- (f)(4) Decedents
  - A covered entity may disclose PHI about an individual who has died to a law enforcement official *for the purposes of alerting law enforcement of the death* of the individual *if the covered entity has a suspicion that such death may have resulted from criminal conduct*

- (f)(5) Crime on premises
  - A covered entity may disclose to a law enforcement official PHI that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred *on the premises of the covered entity*

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- (f)(6) Reporting a crime in emergencies
  - A covered health care provider providing emergency health care in response to a medical emergency, *other than such emergency on the premises of the covered health care provider*, may disclose PHI to a law enforcement official

However,

If the covered health care provider believes that the emergency treatment is needed as a result of abuse, neglect, or domestic violence of the individual, section (f)(6) does not authorize disclosure. Disclosure may only be made as permitted by the HIPAA sections relating to victims of abuse, neglect or domestic violence (no reporting *per se*, comes under mandatory reporting of wounds of violence)

Scenario #2
Can the Hospital do This?

- The "unarrest" scenario is usually intended to avoid financial responsibility for the medical treatment
- If no longer in custody or under arrest, there is no HIPAA exception that applies to permit voluntarily telling the officers when the patient is ready to be discharged
- Exception in Iowa; Iowa Code 229.22 "Ed Thomas" law

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Scenario #3

A patient admitted to an inpatient BHU becomes agitated and aggressive. The capabilities of the BHU staff to manage the patient are exceeded and a security officer is called. By the time the security officer arrives, the patient has broken a leg off a chair and is in a patient room with a nurse threatening her with it.

What Should Be Done?

- In general, CMS expects BHUs to be able to handle the patients it admits in the therapeutic milieu using therapeutic interventions

What Are Therapeutic Interventions?

- Early identification
- De-escalation techniques
- Meds
- Non-violet intervention, e.g., "Dr. Strong" code
- Chemical and physical restraints
- Seclusion

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What Should Be Done?

- Not to rely on security guards or local law enforcement to manage unruly patients in the usual course of business
- Critical Facts: admissions policy/practices, staffing, training

What About Admissions Policies?

- Must a hospital admit all patients?
  - Public hospital?
  - Private hospital?
  - With or without BHU?

Admission Policy:

- Basic description of capabilities
  - Staffing
  - Physical facilities
  - Training of staff
  - Availability of back-up

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Admission Decision:

- Basic capabilities, PLUS
  - Consideration of the immediate milieu
  - How many other challenging patients on the unit right now?

What About Security Guards?

- Not considered therapeutic staff although hospital security officers (employed or contracted) can wear 2 hats and be trained to participate in codes to manage unruly patients
- Concept of the "clinical ceiling"

- Failure to meet CoP standards can result in "immediate jeopardy" findings on survey (CMS) and punitive measures by state licensure authorities
- Can the police ever be called? Yes, in dire circumstances when it is apparent that the capabilities of staff and security have been exceeded
- Threat of serious harm
- Crime being committed

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Neb. Rev. Stat. § 28-929 *et seq.*

- Nebraska Assault on a Health Care Professional
  - Knowing/intentional
  - Serious bodily injury
  - To a peace officer, probation officer or Department of Corrections employee, or
  - A health care professional*

"Health care professional" is a physician or other health care practitioner who is licensed, certified, or registered to perform specified health care services consistent with state law who practices at a hospital or health clinic

Iowa Code 708.3A

"A person who commits an assault as defined in section 708.1, against a peace officer, jailer, correctional staff, member or employee of the board of parole, health care provider, employee of the department of human services, employee of the department of revenue, or fire fighter, whether paid or volunteer, with the knowledge that the person against whom the assault is committed is a peace officer, jailer, correctional staff, member or employee of the board of parole, health care provider, employee of the department of human services, employee of the department of revenue, or fire fighter and with the intent to inflict a serious injury upon the peace officer, jailer, correctional staff, member or employee of the board of parole, health care provider, employee of the department of human services, employee of the department of revenue, or fire fighter, is guilty of a class "D" felony."

Medicare Conditions of Participation for Hospitals

"All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time."

42 CFR § 482-13(c)

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Scope of the Rules

- Applies to all hospital patients wherever located
- Applies to interventions by hospital staff (employees or agents) with registered/admitted patients
- Does not apply to on-duty law enforcement officers
  - In control of a patient being admitted
  - In control of a patient being "EPC'd"
  - Responding to a call for assistance from the hospital
- Does not apply to intervention with non-patients, e.g., visitors, relatives, employees, volunteers, vendors, students

Law Enforcement Restraints Distinguished

The regulations do not apply to "law enforcement" restraint devices such as handcuffs or shackles used with patients by law enforcement officers in the line of duty for custody, detention or public safety purposes

CMS Publ'n 100-07 (State Operations Manual) App'x A Tag A-0154

Such restraints may be applied by law enforcement officers who remain with the patient at all times

Joint Commission Patient Rights' Standards

- "The use of mechanical restraint and seclusion as treatment interventions is prohibited except for patients who exhibit intractable behavior that is severely self-injurious or injurious to others, who have not responded to traditional interventions and who are unable to contract with staff for safety…"

Comprehensive Accreditation Manual for Hospitals (CAMC) at Std. PC.01.01.03 (EP4); see also CAMC at Std. PC.03.03.11

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Scenario #4

- A visitor in the surgery waiting room becomes unruly and assaultive; can security (if available) or local law enforcement be called?
- If security is called, must they use therapeutic interventions?
- CoPs only apply to patients, not visitors to the hospital

Community Coordination/Innovation

- Not just the hospital's problem
- Convene the parties
- Exchange information
- Provide education as necessary
- Improve processes for inter-agency community
- Debrief problem situations as a group

Innovations

- "One Stop Shop" admission line for BHU
- Iowa DIA – bed tracking
- Iowa Interstate placement (SF 440)

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Other Developments

- Nebraska
  - LR 295
  - LR 34
- Iowa
  - IHA legislative agenda, payment for mental health services for patients in custody

Questions?

Thank You

Julie A. Knutson
(402) 636-8327
jknutson@bairdholm.com

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