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—from a declaration of the American Bar Association

An Updated Instruction Manual: How the New NPDB Guidebook Changes the Game

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Do you like *Monopoly? Scrabble?* Choose a board game you enjoy and imagine playing the game with family and friends. Part of the fun is that everyone understands how to play the game and how to apply the rules. You have all played the game for years—dice are rolled with ease and pieces advance quickly. There is no need to consult the instructions.

Now imagine that the game makers release a new edition of your favorite game. Along with an updated, modern design, the game makers release an updated instruction manual. The basic structure of the game is the same, but there are new twists you might not notice unless you scrutinize the new instructions. Now when you play the game, you no longer move with confident ease. The first few times, at least, you must carefully consult the instruction manual to be sure you are playing the game correctly. You must consider how to adjust your strategy because the rules have changed.

You have just imagined what health care attorneys, hospital administrators, and health care practitioners across the county have experienced with the release of the updated National Practitioner Data Bank (Data Bank) Guidebook (Guidebook).[1] The U.S. Department of Health and Human Services (HHS) recently updated the Guidebook for the first time in nearly 15 years. Throughout those 15 years, health care entities across the country developed bylaws, rules and regulations, policies, and practices to govern themselves in accordance with the Guidebook. This article discusses how the updates to the Guidebook may influence hospitals and other health care entities' medical staff bylaws (Bylaws),[2] and written policies and practices for ensuring compliance with the Data Bank requirements.

A Brief History of the Data Bank Guidebook

In 1986, Congress enacted the Health Care Quality Improvement Act (HCQIA)[3] because it recognized that an increasing occurrence of medical malpractice litigation had become a nationwide problem, and it saw a national need to restrict the ability of physicians with histories of professional competence and/or conduct issues to move easily from state to state. Congress viewed effective, professional peer review as a solution

to the nationwide need to improve quality of care, yet the threat of damage claims unreasonably discouraged participation in medical peer review. To address these concerns, HCQIA created a statutory presumption of immunity for those participating in peer review, so long as affected practitioners are provided with an opportunity of due process in connection with a restriction of privileges and membership.

HCQIA also laid the groundwork for the creation of the Data Bank. The Data Bank serves as a clearinghouse that collects and releases information related to the professional competence and conduct of physicians and dentists, and in some cases, other health care practitioners. Various health care entities must report to and query the Data Bank. For example, hospitals must query the Data Bank when processing a physician's application for privileges. For the query to produce reliable, accurate, and up-to-date results, the Data Bank requires hospitals and other health care entities to report certain actions to the Data Bank when those actions restrict a physician's privileges or when a physician resigns during, or to avoid, an investigation of her privileges. The Data Bank's goal is for health care entities to effectively communicate with each other and share information about actions that affect a practitioner's professional competence and/or conduct.

2001: The First Data Bank Guidebook Is Released

Though created by the HCQIA, the Data Bank and its Guidebook are governed by several statutes: Title IV of the HCQIA, Public Law 99-660; Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, codified as Section 1921 of the Social Security Act; and Section 221(a) of the Health Insurance Portability and Accountability Act, Public Law 104-191, codified as Section 1128E of the Social Security Act. In September 2001, HHS issued the first Data Bank Guidebook as a policy manual to assist in understanding how these statutes apply to various health care entities and the intricacies of each of the statutes.

The 2001 Data Bank Guidebook (2001 Guidebook) gave health care entities across the country necessary guidance and instruction on how to comply with the numerous governing statutes. The 2001 Guidebook proved especially helpful with its specific examples and specialized guidance. As a natural result, hospitals and other health care entities developed Bylaws and other written policies and practices to ensure compliance with the 2001 Guidebook. For example, hospitals developed policies and practices to provide the required due process to practitioners, if timely requested, in connection with a restriction of privileges and membership. Hospitals did this to ensure their peer review committees qualified for the statutory presumption of immunity. Approximately 15 years later, the Guidebook's long-awaited update (2015 Guidebook) now requires hospitals and other health care entities to reevaluate their Bylaws and consider what changes are required to comply with the updated guidance.

Discussed more below, the Data Bank requires health care entities to report specific actions concerning physicians and dentists. This article focuses on a hospital or health care entity's requirement to report "adverse clinical privilege actions" to the Data Bank. The phrase adverse clinical privilege actions specifically includes reducing, restricting, suspending, revoking, denying, or failing to renew a practitioner's clinical privileges or membership.[4]

2015: New Guidebook Released—Expands Interpretation of Reportable Actions

The 2015 Guidebook expresses the Data Bank's belief that health care entities are not reporting all events required under its governing laws and regulations. To address this perceived lack of reporting, the 2015 Guidebook states more than once that the Data Bank will not defer to a health care entity's Bylaws or written policies when determining whether an action meets reporting requirements. This is clear under the Data Bank's new language regarding reporting "Summary Suspensions" and "Resignation While Under Investigation" and deserves a health care entity's attention and consideration.

Reporting Summary Suspensions Based on Data Bank's Reporting Criteria, Not Specific Name Assigned by Health Care Entity

The Data Bank and its controlling laws and regulations require that when a physician's or dentist's privileges are suspended for more than 30 days based on professional competence or conduct that the hospital believes adversely affects or could adversely affect the health or welfare of a patient as the result of a professional review action taken by a health care entity, a report must be made no later than the 31st day of the suspension.[5] Many hospital Bylaws and policies address this basic notion. The updated language of the 2015 Guidebook, however, advises health care entities that whether an action is reportable depends on if it meets the Data Bank's reporting criteria, and not the particular name the health care entity uses to describe the action.

Specifically, the 2015 Guidebook states:

- *A suspension or restriction of clinical privileges is reportable if it meets reporting criteria,* whether the suspension or restriction is called summary, immediate, emergency, precautionary, or any other term.
- An action must be reported to the Data Bank based on whether it satisfies Data Bank reporting requirements and *not based on the name affixed to the action.*[6]

If a health care entity's written policies reflect that a restriction of clinical privileges that otherwise meets the Data Bank's reporting criteria does not require a report to the Data Bank because of the name affixed to the restriction, such policies must be updated. Health care entities' written policies should be consistent with the notion that a "suspension" is reportable so long as it meets reporting criteria.

A health care entity is not required to state whether an action is reportable to the Data Bank in its Bylaws or written policies. To the extent a health care entity has chosen to include such language in its governing documents, these documents may continue to use terms including "immediate, emergency, precautionary" or other adjectives to describe suspensions—so long as the documents also reflect that a suspension must be reported when it meets the Data Bank's reporting criteria.

Reporting Resignation While Under Investigation; Data Bank Retains Ultimate Authority

The 2015 Guidebook's interpretation of the term investigation is another example of the Data Bank's message to health care entities that not all required actions are being reported. While investigations themselves are not reportable, health care entities must report a practitioner who resigns his privileges while under investigation, fails to renew privileges while under investigation, or who resigns his or her privileges to avoid an investigation.[7]

Once again, the new Data Bank language makes clear that the Data Bank will not defer to a health care entity's term or description of events when determining whether an action must be reported. The Data Bank states in the new 2015 Guidebook:

> NPDB interprets the word 'investigation' expansively. It may look at a health care entity's bylaws and other documents for assistance in determining whether an investigation has started or is ongoing, but *it retains the ultimate authority to determine whether an investigation exists*.[8]

Many health care entities' Bylaws and written policies draw a bright line to mark when an investigation begins. Some Bylaws require an official vote by the Medical Executive Committee to commence a "formal investigation." This meant that prior to the 2015 Guidebook, a practitioner's resignation or surrender of privileges before the commencement of an official investigation under the Bylaws was often not considered a resignation of privileges while under investigation— because no investigation had been "formally" opened. The 2015 Guidebook challenges that outcome.

The Data Bank's self-described expansive view of investigation is a game-changer. Physicians, committees, and administration working under the 2001 Guidebook understood when a report for resigning while under investigation was required. Under the new guidance, the Data Bank retains the "ultimate authority" to determine whether an investigation had commenced at the time of a physician's resignation. Now the question presents itself: if a health care entity cannot rely on its Bylaws to determine when an investigation has begun, how does a health care entity determine when a physician has resigned while under investigation?

The 2015 Guidebook provides new guidance regarding when an investigation has begun. Health care entities are told that the investigation must:

- Be focused on the practitioner in question;
- Concern the professional competence and/or professional conduct of the practitioner in question;
- Generally should be the precursor to a professional review action;
- Is not a routine or general review of cases; and
- Is not a routine review of a particular practitioner.[9]

Health care entities must be aware of the 2015 Guidebook's new investigation criteria, consider how their controlling Bylaws and other written policies define an investigation, and ensure such documents are consistent with the updated language of the 2015 Guidebook. (*Editor's Note: For more information on resignation of privileges while under investigation, please see "Resignation of Privileges Prior to Notice of a Formal Investigation: Beware of Falling Into a Reporting Trap," published on page 5 of this newsletter.*)

Updated Guidebook Creates New Reporting Requirement for Proctoring

The Data Bank's updated proctoring requirements are another notable change. In the 2001 Guidebook, a hospital's requirement that a proctor only be present during a physician's procedures was not reportable. Under the 2015 Guidebook, however, the requirement that a proctor be present for a physician's procedures for more than 30 days is reportable if imposed based on an assessment of professional competence. Numerous practitioner improvement policies and Bylaws may list the imposition of an observant-only proctor as an action that specifically does not trigger any Data Bank reporting requirement. Such a statement is now inaccurate, and hospitals should amend such policies. Further, many of these same policies likely do not recognize that such a proctoring requirement now provides a practitioner with the right to request a due process hearing to determine the appropriateness of the proctoring requirement.

Updated Guidebook Answers Open Question on Suspensions

Numerous hospital and other health care entity Bylaws and related policies provide that while a summary suspension may be imposed by an individual at the entity, the suspension must be reviewed and confirmed by a larger committee within a certain time. Under the 2001 Guidebook, it was unclear whether a summary suspension was in effect as of the date it was imposed by the initial individual, or when it was reviewed and confirmed by the greater body. This led to the inevitable question of when the clock begins running on the 30-day reporting period.

The 2015 Guidebook addresses this confusion:

> If a summary suspension is confirmed by a review body, the action is considered to have taken effect when it was *first imposed* by a hospital official.[10]

Simply put, the 30-day period begins as soon as the suspension is implemented. Bylaws or policies that provide that a summary suspension is not in effect until confirmed by a higher body are now outdated and require updating.

Health Care Entities Should Review Governing Documents to Ensure Compliance with the 2015 Guidebook's Criteria

It is likely that most health care entities' Bylaws and other policies are affected by the 2015 Guidebook. To meet HCQIA's due process requirement, a hospital or other health care entity's Bylaws should address the requirements for privileges and membership at the facility, the procedures for restricting or reducing a practitioner's privileges, the rights provided to a practitioner to request a fair hearing, and when that right is triggered. Other written policies and practices likely address how an entity may determine whether to take an action that adversely affects a health care practitioner's privileges. The Bylaws or other hospital policies may address how the Credentials Committee evaluates and weighs a report from the Data Bank when reviewing a practitioner's application for privileges.

One must also be aware of whether the health care entity is in a state where a hospital's Bylaws are considered a contract between the medical staff and the hospital. Such hospitals should consider whether their Bylaws specify an action that contradicts the Data Bank's guidance. Hospitals may consider updating their Bylaws and other written policies to reflect that the Data Bank and HHS reserve the right to change and update the guidance provided by the Data Bank Guidebook, and hospitals and health care entities are required to and will act in accordance with the Data Bank's guidance.

Depending on a health care entity's individual Bylaws and written policies, the new 2015 Guidebook may require revisions to ensure administration, medical staff, and attorneys are following the Data Bank's revised instruction manual and there is not a conflict between the health care entity's governing documents and the Data Bank's current guidance.

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1 *Available at* www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp.
2 "Bylaws" as used in this article at all times refer to a health care entity's Medical Staff Bylaws.
3 42 U.S.C. § 11101 *et seq.*
4 41 U.S.C. § 11151(1).
5 *See* 2015 Guidebook at E-35.
6 *Id.* at E-36, 37 (emphasis added).
7 *See id.* at E-34.
8 *Id.* (emphasis added).
9 *See id.*at E-34-35.
10 *See id.* at E-36 (emphasis added).

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Resignation of Privileges Prior to Notice of a Formal Investigation: Beware of Falling into a Reporting Trap

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It is a common misconception that practitioners may resign clinical privileges in a health care entity or membership in a managed care program, medical society, or association at any time without repercussions prior to being provided notice of a formal investigation being initiated against that practitioner. However, such failure to receive notification is not necessarily sufficient to avoid a report to the National Practitioner Data Bank (NPDB). Importantly, it is irrelevant if the reason for the resignation is to avoid the investigation or any subsequent report being made to NPDB.

NPDB was established to serve as a national repository for information related to professional competency and conduct for certain health care professionals. This database assists in ensuring that the professional history of the practitioner is available in any geographic area by entities that are credentialing or otherwise ascertaining the practitioner's professional competence. However, with the publication of the new edition of the NPDB Guidebook[1] in April 2015 and the guidance contained therein, reporting requirements have been expanded and sections regarding notice of actions, the status of investigations, and the ability to resign privileges or memberships without adverse events occurring have been clarified. The practitioner and those advising him, and the entities conducting such investigations, should be cognizant that reporting requirements are more expansive than in the past, and the previous misconceptions now create additional reporting traps.

National Practitioner Data Bank

The Health Care Quality Improvement Act of 1986 (HCQIA)[2] requires the reporting of medical malpractice payments and certain adverse actions levied against physicians as it relates to professional conduct or competency.[3] Prior to its passage, it was common for practitioners who had been subject to such adverse acts to relocate to other states. Accordingly, the entity investigating the practitioner would have to rely on what he disclosed in his application and supporting documentation tendered at the time the application was made. With a lack of a nationwide database, the entity would be hindered from otherwise being able to complete a full investigation of the practitioner. NPDB was developed to allow for such a database.

Before the recent update, the last version of the NPDB Guidebook was published in 2001.[4] The 2015 version expanded reporting requirements and provided additional guidance for mandatory reporting related to resignations under investigation, as well as non-renewal and expiration of privileges while under investigation. The 2015 version generated controversy due to the determination of the type of investigation that leads to a reportable event and specific clarification that a practitioner need not have knowledge of an ongoing investigation to be subject to NPDB reporting if he resigns his privileges or otherwise fails to renew them.[5] The revised NPDB Guidebook now provides that the term "investigation" is interpreted "expansively."[6] In determining what is meant by, and the time period of, an investigation, the NPDB may look at the health care entity's bylaws and other governance or operational documents to determine when an investigation has been initiated or is currently ongoing.[7] However, those resources, even if they define investigation, are not controlling. Ultimately, the NPDB has the sole authority to determine the existence and time period of an investigation.[8]

HCQIA Reporting Requirements

The HCQIA establishes two instances when a hospital must file a report with the NPDB: (1) when it "takes a professional review action that adversely affects the clinical privileges of a physician for a period of longer than 30 days"[9]; and (2) when it "accepts the surrender of clinical privileges of a physician (i) while the physician *is under investigation by the entity* relating to possible incompetence or improper professional conduct, or (ii) in return for not conducting such an investigation or proceeding."[10] This article focuses on when a practitioner is "under investigation" and what constitutes a resignation that triggers NPDB reporting.

What Type of "Investigation" Leads to a Reportable Event?

The issue of what constitutes an "investigation" that would lead to a reportable event is dependent on the determination of whether an investigation is ongoing, what party is conducting the investigation, and the investigation's purpose. As previously discussed, NPDB maintains broad discretion in determining what constitutes an investigation. It considers an investigation to encompass all of its aspects, from the beginning stages of the inquiry, such as fact gathering, until a final decision has been issued related to clinical privileges.[11] It does not take a formal inquiry to be considered an investigation.

As part of this determination, the next issue to be addressed is who exactly is conducting the investigation? In *Simpkins v. Shalala*,[12] the U.S. District Court for the District of Columbia held that HCQIA's reporting requirements are not automatically triggered when an individual supervisor is investigating

the physician.[13] Rather, there must be a determination as to the capacity of authority held by the party conducting the investigation to determine whether it should be reported. In *Simpkins*, the court ruled that reporting is required when there is a "formal action by the hospital" because it is the "health care entity."[14] In this scenario, a departmental review process (or a Focused Professional Practice Evaluation (FPPE) using The Joint Commission terminology) did not constitute an investigation by a health care entity for reporting purposes under NPDB, unless it can be demonstrated that the action of a supervisor constituted an action of the hospital.[15]

The Kentucky Court of Appeals in *Omar v. Jewish Hospital Healthcare Services*[16] noted that the HCQIA does not define the term investigation.[17] Rather, citing the 2001 version of the Guidebook, the court held that "factors indicative of an investigation include scrutiny carried out by the health-care entity as opposed to an individual on staff, scrutiny focused on the physician and concerned with his professional competence, and scrutiny that is a precursor to a professional review action."[18] In Omar, the physician was the subject of a formal corrective action investigation initiated by the Medical Executive Committee pursuant to the Bylaws, which was clearly an action by an entity rather than the limited action at issue in Simpkins.

So how does a practitioner know whether resigning his privileges or membership during an investigation is a reportable event? The next step is determining whether the investigation pertains to "possible incompetency or improper professional conduct."[19] If so, a resignation of privileges or membership during the investigation may be reportable depending on, as discussed above, who is conducting the investigation. If the investigation involves "individual action" by a person like a departmental supervisor as in *Simpkins*, then reporting is not triggered *unless* that person had the authority to represent the health care entity and issue a final determination. However, if the investigation is undertaken by the health care entity itself or a committee of the entity as in *Omar*, then reporting would be required.

What Is Considered a Resignation Under Investigation?

The 2015 Guidebook expanded the reportability of a resignation during an investigation because it now has more authority to define what constitutes an investigation. In the 2015 Guidebook, NPDB provided significant guidance, including examples, as to when a resignation is reportable and why.[20] It should be noted that in some of the examples, the physician is not aware of the investigation. *Importantly, the 2015 Guidebook makes clear that notice of the investigation is immaterial.* The following are examples from the Guidebook of a resignation or surrender of privileges and the reasoning for whether it is reportable:

- A physician withdraws his reapplication for privileges or membership or allows for such to expire without any effort to reapply while unaware of an ongoing investigation due to quality complaints. The surrender is reportable. The organization must produce sufficient evidence that the investigation occurred prior to the surrender. The physician's knowledge of the investigation is immaterial.[21]
- A hospital begins a review of issues related to professional competence just prior to the expiration of privileges and the physician fails to renew the clinical privileges. The surrender is reportable. Again, the physician's knowledge of the investigation is not required for it to be reportable. The failure to renew the clinical privileges is the equivalent of a surrender.[22]
- A preferred provider organization is investigating a member physician as a result of quality of care complaints. The physician has not been provided notice of the investigation. While the investigation is ongoing, she resigns her plan membership. The resignation is reportable. Again, even in this scenario, the physician's lack of knowledge is immaterial.[23]
- A physician is being investigated for professional competence but resigns his privileges because the physician plans to move to another state. The surrender is reportable. NPDB was created to ensure physicians with issues of professional competence are tracked when they move to other states.[24]
- A physician that is the subject of an investigation is offered the ability to stay at the hospital under some restrictions on her privileges. The physician refuses the agreement and resigns her privileges. The physician contended the investigation had concluded because of the offer and therefore the resignation of privileges was not reportable. In reality the heath care entity's decision-making authority must either formally close the investigation or move forward with a final action for the investigation to be concluded. Here, the physician was simply offered an agreed-upon resolution, which she refused. Because the offer was not a final disposition, the investigation was ongoing and the resignation was reportable.[25]
- A hospital initiates an investigation of a physician who is the subject of numerous quality-of-care complaints. The physician resigns his privileges but no professional review action was taken. The resignation is reportable because the investigation was triggered by professional competency complaints and was outside a routine review of the medical staff.[26]
- A physician resigns his privileges while a routine review is being conducted that applies to all practitioners holding clinical privileges. This resignation is not reportable because it is not directed at a specific physician.[27]

Conclusion

As the above examples demonstrate, a physician should be proactive in determining whether he is under any type of investigation relating to professional competence or quality-of-care concerns before resigning or deciding not to renew his privileges or memberships. A health care entity in that instance has an affirmative obligation to report a resignation or failure to reapply if it occurs during such an ongoing investigation. Notably, reporting is mandatory whether or not it is a formal investigation, and regardless of whether the physician has been notified of such investigation.

A surrender of privileges during a routine investigation of a departmental or medical staff should not be problematic. However, if a targeted investigation of a specific physician's clinical competency results in the process of the routine review, the physician must recognize that any failure to maintain privileges and follow through with the investigation until a formal resolution has occurred is reportable to NPDB.

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1 *Available at* www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp.
2 42 U.S.C. § 11101 *et seq.*
3 42 U.S.C. §§ 11131-11133.
4 *Available at* www.ire.org/media/uploads/files/datalibrary/npdb/guidebook.pdf.
5 *See* Markos, J., *Getting to Know the NPDB*, Chicago Med., 118(6), 12-13 (2015), *available at,* www.cmsdocs.org/news-publications/chicago-medicine-magazine/2015-issues/June2015.pdf; Maruca, W., *NPDB Guidebook revision would clarify investigation reporting issues*, Allegheny County Med. Soc'y Bulletin, 105(7), 524-526 (2015), *available at* www.acms.org/bulletin/2015/15jul.pdf; Cassidy, M., *NPDB Guidebook revision would clarify investigation reporting issues*, Allegheny County Med. Soc'y Bulletin, *103*(12), 524-526, 528 (2013), *available at* www.acms.org/bulletin/2013/13dec.pdf.
6 NPDB Guidebook; Chapter E: Reports, pp. E-34.
7 *Id.*
8 *Id.*
9 42 U.S.C. § 11133(a)(1)(A).
10 42 U.S.C. § 11133(a)(1)(B) (*emphasis added*).
11 NPDB Guidebook; Chapter E: Reports, pp. E-34.
12 999 F. Supp. 106 (D.D.C. 1998).
13 *Id.* at 114.
14 *Id.*
15 *Id.*
16 153 S.W.3d 845 (Ky. Ct. App. 2004).
17 *Id.* at 848.
18 *Id.*
19 42 U.S.C. § 42 U.S.C. 11133(a)(1)(B).
20 NPDB Guidebook, pp. E-29-E57.
21 NPDB Guidebook; Chapter E: Reports, pp. E-33-E-34.
22 NPDB Guidebook, Q&A: Reporting Clinical Privileges, Number 18, *available at* www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp?page=EClinicalPrivilegesQA.jsp.
23 *Id.* at Number 11.
24 *Id.* at Number 20.
25 *Id.* at Number 23.
26 *Id.* at Number 24.
27 *Id.* at, Number 25.

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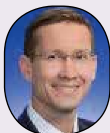

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Critical Access Hospitals Meet EMTALA and Supervisory Requirements with PAs, NPs, and Telemedicine

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Emergency Department (ED) staffing varies significantly among critical access hospitals (CAHs). Some are situated in locations with a substantial population and have significant volume coming through the Department, so it makes sense to staff the ED with a physician on site on a 24-hour-a-day, seven-day-a-week basis. However, many CAHs are located in remote areas and have a limited number of qualified practitioners available locally to provide on-call coverage. In these cases, the CAHs rely heavily on advanced practice clinicians (APCs), usually physician assistants (PAs) and nurse practitioners (NPs).

Increasingly, CAHs' network hospitals are offering a telemedicine service with consultation available by an ED physician (EDP) and/or other specialists to support the CAH ED practitioners. In those communities with limited ED practitioners and/or budgetary constraints, the question arises whether the physician available by telemedicine can do any or all of the following when an APC is serving on-call for the CAH:

1. Serve as the physician who certifies that the benefits of transfer outweigh the risks, as required by the Emergency Medical Treatment and Labor Act (EMTALA) for most transfers;
2. Serve as the on-call physician, meeting EMTALA's requirement that a physician serve on-call even when an APC is taking primary call; and
3. Meet state requirements for supervision or collaboration of a PA or NP working in the CAH's ED.

If the physician available for emergency telemedicine services can perform these three functions, it would be unnecessary for a local physician on the CAH's medical staff to serve on-call while an APC was serving as the primary on-call practitioner. This would be beneficial for lifestyle purposes by allowing the local physicians to leave the local community more freely and more often. It also would allow the CAH to avoid the cost of the local physician's services, in addition to the emergency telemedicine coverage and the APC's coverage.

This article addresses the challenges of using remote physicians in EDs and analyzes specific considerations under state law that must be addressed.

Physician Certification That Benefits of Transfer Outweigh Risks

Unless the ED patient (or a legally responsible person acting on the patient's behalf) requests transfer, a physician is required to certify that the benefits of transfer outweigh the risks of transfer. Specifically, EMTALA regulations provide these two alternatives, depending on whether a physician is present in the ED:

> (B) A physician (within the meaning of Section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or
>
> (C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in Section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.[1]

On the face of the regulation, it appears that a physician available via telemedicine could consult with a CAH non-physician practitioner, agree with the certification that benefits outweigh risks of transfer, and then subsequently countersign the certification by electronic or faxed signature. The Centers for Medicare & Medicaid Services (CMS) regional offices generally have recognized that the countersignature does not have to precede the patient's transfer.

The analysis must proceed, however, to general medical staff credentialing considerations:

1. Is the telemedicine physician credentialed by the CAH's medical staff and governing board, and granted clinical privileges of a nature to support her documentation in the patient's medical record?

While the physician certification is not an order as such, it is a precondition for transfer if the patient is in an unstabilized emergency medical condition. Thus, the physician's countersignature of the certification influences diagnosis and treatment. That being the case, most hospitals would find it necessary to credential the telemedicine physician. This can be burdensome if the service providing emergency telemedicine uses a large number of physicians. It could be made a term of the emergency telemedicine service that the

contractor pay a reasonable fee for credentialing of physicians exceeding a reasonable number, if the CAH does not charge such a fee for all applicants.

2. Is the telemedicine physician licensed in the state where the CAH is located?

While many states' physician licensure statutes have exceptions allowing physician prescriptions and outpatient orders to cross state lines, most states have not gone so far as to allow telemedicine to cross state lines without the physician obtaining a license in the state where the patient will be diagnosed or treated.

On-Call Physician from Distant Site

The physician on-call requirement is found in Section 1866 of the Social Security Act.[2] This section outlines the requirements included in the Medicare provider agreement for hospitals. Section 1867, which sets forth the EMTALA requirements, provides for enforcement against hospitals and physicians when an on-call physician fails or refuses to appear within a reasonable time after being notified to appear. This is a stumbling block for a CAH's reliance on a telemedicine physician to serve as the on-call physician because the telemedicine physician is not typically within a proximity that would allow him to come to the CAH within a reasonable time after being requested to appear. The CMS Interpretive Guidelines for EMTALA address this problem:

> There is no EMTALA prohibition against the treating physician consulting on a case with another physician, who may or may not be on the hospital's on-call list, by telephone, video conferencing, transmission of test results, or any other means of communication. CMS is aware that it is increasingly common for hospitals to use telecommunications to exchange imaging studies, laboratory results, EKGs, real-time audio and video images of patients and/or other clinical information with a consulting physician not on the hospital's premises. Such practices may contribute to improved patient safety and efficiency of care. In some cases it may be understood by the hospitals and physicians who establish such remote consulting arrangements that the physician consultant is not available for an in-person assessment of the individual at the treating physician's hospital. However, if a physician:
>
> - is on a hospital's on-call list;
> - has been requested by the treating physician to appear at the hospital; and
> - fails or refuses to appear within a reasonable period of time;
>
> then the hospital and the on-call physician may be subject to sanctions for violation of the EMTALA statutory requirements.[3]

The Interpretive Guidelines seem to allow the telemedicine physician to act as the on-call physician, with the advance agreement that no CAH ED practitioner will ever ask that

the telemedicine physician travel to the CAH to serve the patient. CMS' warning about the consequences of a failure or refusal to come to the CAH certainly serves as a caution to a telemedicine physician, who should be concerned if a CAH ED practitioner were to ask the telemedicine physician to come to the CAH to attend the patient. He could be at risk of civil monetary penalties for a failure or refusal to come to the CAH. However, it seems apparent that any CAH ED practitioner would recognize in advance that the telemedicine physician is not available to travel to the CAH, but only to consult by telecommunication and to help facilitate transfer. That should be stated clearly in the contract for emergency telemedicine services.

PA and NP Supervision/Collaboration from Distant Site

State law requirements for supervision and/or collaboration by a physician providing care via telemedicine vary significantly from state to state. To illustrate some of the potential issues with utilizing an emergency telemedicine physician as a supervising physician for APCs, this article reviews Nebraska laws regarding supervision of PAs:[4]

1. *In order to supervise a Nebraska-licensed PA, a physician must hold a Nebraska license to practice medicine.*[5] With most telemedicine services, the physicians seek and obtain licensure in all states where they intend to contract to provide services. This is not an impediment to naming the emergency telemedicine physician as the supervising physician.
2. *A supervising physician must maintain a written and executed supervisory agreement with each PA he/she 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.*[6] It would probably not be required of a backup physician that she maintains a supervisory agreement with PAs who are otherwise supervised by a local physician. However, there is no regulatory instruction on how a physician should be identified as a backup physician.
3. *The supervising physician must maintain a copy of the supervisory agreement on file at his/her primary practice site as well as at the practice site where the PA provides medical services.*[7] It would make sense for any physician who was going to serve as a backup physician to obtain a copy of the PA's supervisory agreement to ensure that the scope of practice allowed to the PA was broad enough to support the ED practice at the CAH.
4. *A licensed physician may supervise no more than four PAs at a time, unless a waiver is granted.*[8] There is no regulatory indication whether there is any such limit on serving as a backup physician. If such a limit applies, this could be prohibitive for emergency telemedicine physicians serving multiple CAHs simultaneously because the number of supervised PAs could be significant at each CAH.
5. *The supervising physician bears strict liability for any negligent act or omission by the PA.*[9] This is a harsh reality for supervising physicians in Nebraska. Most choose to ignore this legal fact, or are shocked to learn it is true. This could reasonably stand as an impediment to an emergency telemedicine physician's willingness to serve as a supervising or backup physician for a Nebraska PA, from a risk management perspective.
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.*[10] This standard would place a heavy burden on the emergency telemedicine physician to be familiar with the PA's training and experience, so as to judge the PA's competence in emergency procedures.
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.*[11] As long as the emergency telemedicine physician served as backup only, and there was another physician serving as the supervising physician more generally, this burden probably would not fall on the telemedicine physician.
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.*[12] This standard seems to allow remote supervision, but for PAs with less than two years' experience or a temporary license,

there are limits on the percentage of time that the PA and supervisor can practice remotely from one another.

9. *The medical services delegated to the PA form a component of the supervising physician's scope of practice*.[13] Some hospitals have interpreted this to require that the supervising physician hold all privileges at the hospital as the PA does. This could complicate the credentialing and privileging of the emergency telemedicine physician. Most hospitals refrain from granting privileges that will never be used because there will be no patient volume to review for quality and meaningful review at the time of reapplication.

10. *In order for a PA to practice in a hospital, the supervising physician must be a member of the hospital's medical staff*.[14] CMS has made it clear that medical staff membership and clinical privileges do not have to go hand in hand. But in this case, for a PA to be supervised by the telemedicine physician, the physician would have to be a member of the CAH medical staff. It might be necessary for the CAH to create a special category of staff for this purpose because emergency telemedicine physicians would not fall within most hospitals' qualifications for courtesy and consulting staff.

Interestingly, the Nebraska legislature has eliminated all supervisory requirements for licensed advance practice registered nurses (NPs) after completion of 2000 clinical hours. So the many impediments to having a telemedicine physician supervising a Nebraska PA stand in sharp contrast to the few that would interfere with the same physician collaborating with a Nebraska-licensed NP.

The Nebraska requirements are used only as an example of state licensing issues, and health care attorneys must familiarize themselves with the specific laws and regulations of each state in which they practice or are involved.

In conclusion, it is possible for a CAH to credential emergency telemedicine physicians to countersign the physician certification as to risks and benefits of transfer, and to serve as an on-call physician (who, by advance agreement, will not be called to the CAH). Depending on the APC's licensure and state, it may be either simple or prohibitive for the same physician to fill the role of a supervising or collaborating physician for purposes of state law for the APC staffing a CAH ED.

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1 42 C.F.R. § 489.24(e)(1)(B) and (C).
2 *See also* 42 C.F.R. § 489.20, establishing contents of the Medicare provider agreement.
3 CMS State Operations Manual, Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, Tag A-2404/C-2404 (Rev. 60, 07-16-2010).
4 A supervising physician for a Nebraska-licensed PA may designate a backup physician to ensure supervision of the PA in the supervising physician's absence. The backup physician is subject to the same requirements as are imposed on the supervising physician when the backup physician is acting as the supervising physician. 172 N.A.C. 90-002.
5 172 N.A.C. 90-006.01.
6 *Id.*, and 172 N.A.C. 90-006.01A.
7 172 N.A.C. 90-006.01B.
8 172 N.A.C. 90-006.01E.
9 172 NAC 90-007.
10 172 NAC 90-006.01D.
11 172 NAC 90-006.08.
12 172 NAC 90-006.01C.
13 172 NAC 90-006.02(3).
14 172 NAC 90-006.06(3).

Telemedicine and Telehealth: Changing the Health Care Delivery Landscape

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In 2014, the *World Market for Telehealth*, a report published by analytics company IHS, predicted that the number of patients using telehealth services will rise from fewer than 350,000 people in 2013 to seven million in 2018.[1] Revenue for telehealth devices and services is expected to reach $4.5 billion, up from $440.6 million in 2013.[2]

The terms "telemedicine" and "telehealth" are sometimes used interchangeably to describe the use of technology to provide health care services. The American Telemedicine Association, an advocacy group that promotes the use of advanced remote medical technology, defines telemedicine as "the use of medical information exchanged from one site to another via electronic communications to improve a patients' clinical health status."[3]

The Federation of State Medical Boards defines telemedicine as "the practice of medicine using electronic communications, information technology or other means between a licensee in one location, and a patient in another location with or without an intervening healthcare provider."[4] The U.S. Department of Health and Human Services defines telehealth as "the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration."[5]

Notably, the primary difference in definitions relates to telemedicine supporting communication exchange from one site to another site regardless of distance, whereas telehealth supports long-distance clinical health care. Telehealth is increasingly becoming an important part of the U.S. medical system that focuses more on quality and integration of care, including highly integrated care models, such as patient-centered medical homes and accountable care organizations.

Coverage of Telemedicine Services by CMS

Access and coverage of telemedicine and telehealth varies. For example, the Centers for Medicare & Medicaid Services (CMS) limits the use of telemedicine for Medicare beneficiaries unless the patient presents at a certain location.[6] Specifically, CMS defines an originating site as the location of an eligible Medicare beneficiary at the time the service furnished via a telecommunications systems occurs. Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in a rural Health Professional Shortage Area (HPSA) location either outside of a Metropolitan Statistical Area (MSA) or in a rural census tract; or a county outside of a MSA. As a condition of payment, the distant site practitioners must use an interactive audio and video telecommunications system that permits real-time communication between the telehealth provider, at the distant site, and the beneficiary, at the originating site.

This differs from another type of telehealth format that uses synchronous "store and forward" technology. This format is the transmission of a patient's medical information from an originating site to a physician or practitioner at the distant site. Yet another type of telehealth format includes technologies such as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devices, which are used to collect and transmit patient data for monitoring and interpretation.

Medicaid views telemedicine as a cost-effective alternative to the traditional face-to-face method of providing medical care. The federal Medicaid program encourages states to use the flexibility inherent in federal law to create innovative payment methodologies for services that incorporate telemedicine technology. Because of this flexibility, states differ in their definitions or regulations that affect who can furnish telemedicine services and reimbursement by Medicaid and private payers.

Developments in the Use of Telemedicine

Despite somewhat-limited coverage for telemedicine by Medicare and Medicaid, data show that patients and health care providers are increasingly open to its use. For example, according to the American Hospital Association (AHA), in 2013 53% of hospitals utilized telehealth, and another 10% were beginning the process of implementing telehealth services.[7] Recent studies on the use of telehealth services have shown that 74% of U.S. consumers would use telehealth services; 76% of patients prioritize access to care over the need for human interactions with their health care providers; 70% of patients are comfortable communicating with their health care providers via text, email, or video, in lieu of seeing them in person; and 30% of patients already use computers or mobile devices to check for medical or diagnostic information.[8]

Of particular value in hospital-based telehealth platforms is that of Tele-ICU. This platform includes networks of audio-visual communication and computer systems linked with critical care physicians and nurses of intensive care units (ICU) in other, often-remote hospitals. Research conducted in 2013 on nearly 120,000 adult patients from 56 ICUs in 32 hospitals concluded that ICU telehealth interventions improved adherence to ICU best practices, reduced response times to alarms, and encouraged the use of performance data.[9] Rural and critical access hospitals are often in need

of critical care clinicians to diagnose, manage, stabilize, and make transfer decisions concerning complex patients. According to AHA, approximately 20% of Americans live in rural areas where many do not have easy access to primary care or specialist services.[10]

The National Rural Health Association (NRHA) recommends the use of emergency telemedicine to solve several rural health care issues including: providing access to specialists regardless of geography; leveraging the mid-level provider workforce; and economically providing immediate access to quality emergency services. The goal of many emergency telemedicine programs is to support the rural physicians and reduce call requirements. Emergency telehealth programs can eliminate the time delay between patient arrival to the rural emergency department and provider arrival to the rural hospital. Over a 12-month period, Avera eEmergency, a service that connects emergency room doctors, provided access to an emergency telehealth physician an average of 18 minutes prior to the arrival of the local physician for 123 cases.[11]

During its fall 2014 meeting in Sioux Falls, SD, the National Advisory Committee on Rural Health and Human Services discussed the use of telehealth in rural areas and how this technology aligns with the emerging focus on value in health care. The Committee concluded that as delivery system reform continues to transition from volume to value, telehealth can provide quality care in rural areas. However, regulatory changes must be made to include more telehealth services and reimbursements for those services, and quality must be reported and monitored.[12]

The ACA includes a number of health care goals: increasing the number of insured, improving quality and outcomes, reducing costs, and testing new approaches for how to reimburse providers and deliver health services. Telehealth may help achieve these aims, particularly in the long term care setting, through an efficient use of resources and a reduction in hospital re-admissions by allowing doctors to give some orders without a patient having to travel to a hospital.

For example, one visiting nurses group has seen improved patient outcomes using telemedicine. Each year, HomeHealth Visiting Nurses (HHVN) of Southern Maine travel more

than 1.6 million miles to provide essential home health service to more than 8,500 patients located in largely rural areas.[13] Maine ranks fourth nationwide for deaths caused by chronic illness, costing about $1.5 billion per year.[14] A significant portion of these costs results from frequent hospitalizations for exacerbations of chronic disease.

From 2011-2013, HHVN cared for more than 12,000 patients with chronic disease, 79.1% of which were diagnosed with health disease or congestive health failure.[15] Approximately 3,200 of these patients received traditional home health care augmented by telehealth monitoring services. Telehealth patients experienced significantly lower rates of hospitalization when compared with HHVN patients who did not receive telehealth.[16] Patients enrolled with telehealth services also demonstrated lower rates of emergent care and an improved ability to manage medications, and were more likely to remain independent at home following discharge from services.[17]

However, telehealth is not just for the elderly population. In 2014, MDLive (a telehealth service provider) hired the Harris Poll to conduct a Mobile Health Index Survey of adults 18-34 years old. The results demonstrated those ages 18-34 are more likely (54%) to postpone or cancel (72%) a visit to a health care provider because of inconvenience. Eighty-two percent preferred consultation over a mobile device.[18]

An April 30, 2015 *New England Journal of Medicine* article addressed confronting the challenges of telehealth, including weak before-and-after studies that rarely examine patient-centered outcomes and instead focused on feasibility and acceptability to patients.[19] The existing literature does not settle the issue of whether telemedicine delivers the same outcomes as face-to-face encounters at either the same or lower costs. Where effectiveness data is available, the influence of telehealth varies greatly depending on where and how the technology is applied. Published studies do little to explain heterogeneity or offer insight into how programs can become more effective. Potential unintended consequences of telehealth are not understood.

In summary, while there is a demonstrated interest and benefit in the use of telemedicine, legal and regulatory infrastructure for telehealth has yet to catch up with the technology. Legal counsel must therefore ensure that clients understand the potential risks of using telemedicine while such legal guidance emerges.

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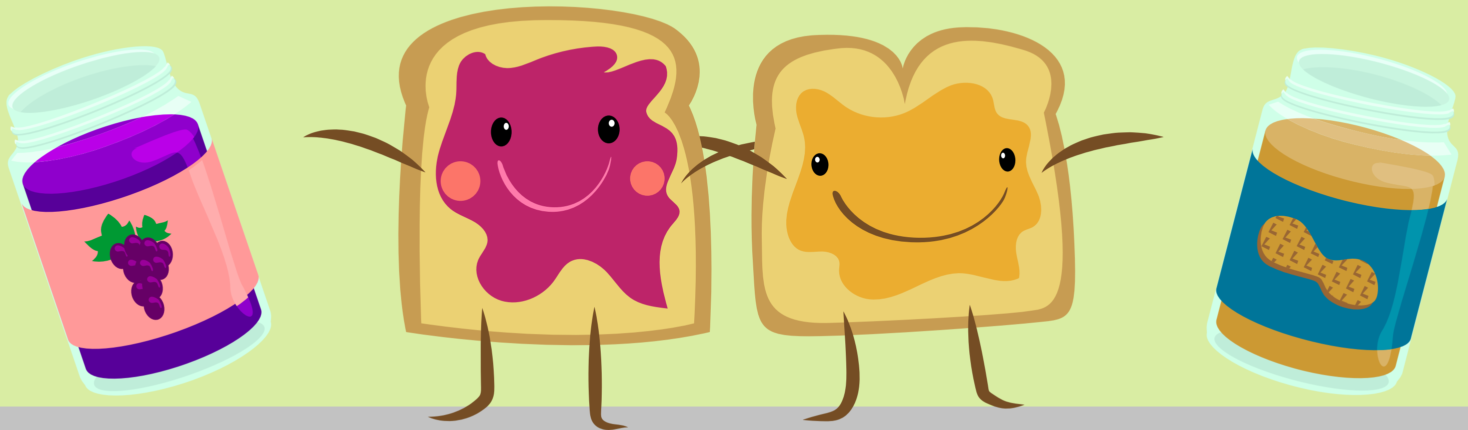

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