POLSINELLI

APRIL 2019 | VOL. 2

Med-Staff Newsletter

QUARTERLY NEWSLETTER FROM THE MEDICAL STAFF PRACTICE GROUP

NATIONAL PRACTITIONER DATA BANK ISSUES OCTOBER 26, 2018 GUIDEBOOK WITH NEW SIGNIFICANT CHANGES

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The National Practitioner Data Bank ("NPDB") quietly published an updated NPDB Guidebook on October 26, 2018 ("2018 Guidebook"). Unlike the previous April 2015 update to the 2001 edition, the NPDB did not issue a provisionary Guidebook or provide opportunity for public review or comment.

Most of the 2018 Guidebook is unchanged; however, there are significant revisions that potentially expand reporting obligations regarding adverse actions against clinical privileges of physicians and dentists. This article summarizes the revisions that relate to reporting clinical privilege actions under the 2018 Guidebook, Chapter E: Reports: Reporting Adverse Clinical Privileges Actions ("Chapter E").

A. New Language: Proctoring Reportable After 30 Days

The 2018 Guidebook revises the language under Chapter E to reflect the opinion it previously stated in a *Policy Corner* publication. Chapter E now provides that if proctoring is imposed as a result of a professional review action related to professional competence or conduct and the period of proctoring lasts for more than 30 days, the action must be reported to the NPDB. *See* 2018 Guidebook, p. E-40.

In contrast, the 2015 Guidebook stated that if a proctor was assigned to a physician or dentist for a period of longer than 30 days the action should be reported. *See* 2015 Guidebook, p. E-37. Based on this language, practitioners' counsel previously argued that the 30-day period did not begin until a proctor was actually "assigned" to the practitioner, as opposed to when the proctor was imposed. The NPDB in the 2018 Guidebook removed the word "assigned" thus reinforcing that the 30-day clock starts at the time the proctoring requirement is imposed.

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Events

Erin Muellenberg will present on **The MSP and the False Claims Act** at the Washington Association of Medical Staff Services ("WAMSS") Annual Education Conference on April 26th in Kennewick, WA

John Synowicki will present on **Physician Drug Use Diversion and Interactive Case Studies – How Would You Handle The Peer Review?** at the Texas Society for Medical Services Specialists ("TSMSS") Annual Education Conference on April 25th in San Antonio, Texas.

John Synowicki will present on **Peer Review of Employed Physicians and Peer Review Sharing Agreements for Affiliated Entities and Academic Medical Centers** at the Nebraska Association of Medical Staff Services ("NeAMSS") Annual Education Conference on April 26th in Lincoln, Nebraska.

Erin Muellenberg will present on **Credentialing and Peer Review** at the Oregon Association of Medical Staff Services ("OAMSS") at the Annual Education Conference on May 9th-10th in Newport, Oregon.

Erin Muellenberg will present on **Credentialing Red Flags & Dr. Death, Leadership Orientation, and Hiding in Plain Sight** at the California Association of Medical Staff Services ("CAMSS") Annual Education Conference on May 24th-25th in Los Angeles, California.

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For purposes of reporting to the NPDB, "proctoring," is considered a restriction because the practitioner cannot perform certain procedures without proctor approval or without the proctor being present during the procedure. *Id*. When either is required, the practitioner's privileges are adversely affected, and the 30-day count begins. *Id*.[1]

B. New Section: Length of Restriction

The NPDB added a new section to Chapter E entitled "Length of Restriction." *See* 2018 Guidebook, p. E-40-41. This section appears to be the NPDB's response to the 2017 federal court decision in *Walker v. Memorial Health System*, No. 2:17-CV-00066-JRG, 2017 WL 514325 (E.D. Tex., February 8, 2017). In *Walker*, the court found that a proctoring requirement for "the next five bowel surgeries" was not reportable because it was for an indefinite period of time; the proctoring requirement, however, was in effect for more than 30 days. In the 2018 Guidebook, the NPDB's position is that a restriction is reportable if it is in effect for more than 30 days, regardless of whether the restriction states that it is for less than 30 days or contains no time limitation like the one in *Walker. Id.*

C. Question 22: Agreement Not to Exercise Privileges May Be Reportable

The 2018 Guidebook added a new question and answer regarding an agreement by the practitioner not to practice.

Question 22:

Is an agreement not to exercise privileges during an investigation, without actually surrendering the privileges, a resignation while under investigation that is reportable?

Answer:

Yes, the agreement not to exercise privileges is reportable if other reportability conditions are met. NPDB regulations state that "acceptance of the surrender of clinical privileges or any restriction of such privileges . . . while under investigation" is reportable. **An agreement not to exercise privileges is a restriction of privileges. Any restriction of privileges while under investigation, temporary or otherwise, is considered a resignation and must be reported.** 2018 Guidebook, p. E-50.

The NPDB's new position that a practitioner's agreement not to exercise privileges is a restriction that is reportable, as a surrender of clinical privileges while under investigation, is a significant departure from past protocol. *Id*. The prior position was that a self-imposed restriction during an investigation was the equivalent of a suspension and not reportable unless in effect for more than 30 days.

This new approach is likely to encourage hospitals to impose short suspensions that are not reportable to the NPDB or adopt an unofficial "off the books" understanding between the hospital and practitioner that the practitioner will not practice for a period of time while the matter is being investigated. This latter position is contrary to the NPDB's official position. Although short suspensions will not be reported to the NPDB, it is likely practitioners will be required to report them on some applications to hospitals for privileges and membership. Also, some state licensing boards require practitioners to report hospital suspensions for less than 31 days. *Id*.

[1]The 2018 Guidebook provides that proctoring which entails retroactive chart review, is not reportable to the NPDB. *Id.*

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D. Question 23: Leave of Absence Reportable If Under or To Avoid Investigation

The 2018 Guidebook contains a new question and answer regarding a practitioner taking a leave of absence, without surrendering privileges.

Question 23:

Is a leave of absence while under investigation considered to be a resignation of privileges that is reportable?

Answer:

If a leave of absence while under investigation restricts privileges, it is reportable. NPDB's regulation states that "[a]cceptance of the surrender of clinical privileges or any restriction of such privileges" is reportable. **To the extent a leave of absence restricts a practitioner's ability to exercise privileges, it is considered a surrender that is reportable.** If a practitioner can take a leave of absence without affecting his or her privileges, and his or her privileges remain intact during the leave of absence, the leave of absence is not reportable to the NPDB. 2018 Guidebook, p. E-50.

This question and answer clarifies a general understanding that the decision by a practitioner to take a leave of absence while under investigation for competence or professional conduct is reportable to the NPDB. Most hospital medical staff bylaws provide that once a leave of absence is taken, the practitioner is required to apply for reinstatement which must be granted before practice can be resumed. It appears the NPDB wants to ensure it is capturing data of a practitioner taking a leave of absence, while under investigation, who may never seek reinstatement to the hospital's medical staff. If the practitioner is reinstated, the hospital would submit a Revision-to-Action Report to the NPDB with this information.

E. Question 24: Reappointment Review May Be an Investigation

The NPDB addresses in the 2018 Guidebook when a practitioner's resignation during the recredentialing process could be reportable to the NPDB.

Question 24:

When does the review of an application for reappointment become an investigation if the physician resigns before final action is taken on the reappointment application? For example, if a physician discloses on an application for reappointment that he/she has been a defendant in three malpractice cases during the last 2 years, and the credentials committee requests additional information about the cases, has an ongoing "routine review" become an "investigation?"

Answer:

It depends. A routine or general review is not considered an investigation. So, for example, if all practitioners are automatically or routinely asked for additional information when they are defendants in a certain number of malpractice cases, this type of request probably would not be considered an investigation. Therefore, the resignation would not be reportable. However, if officials at the reappointing hospital had specific concerns about this practitioner's competence based on the number or severity of the medical malpractice cases, then the inquiry appears to deviate from routine review, be focused on a particular practitioner, and concerns competence and conduct issues. In this situation, the activity may be seen as an investigation, and, if so, the resignation would be reportable. 2018 Guidebook, p. E-50-51.

Pursuant to Question 24, if a hospital establishes a routine practice of questioning application responses that fall outside the norm, a NPDB report may not be necessary if the practitioner resigns during the credentialing process. The "routine practice" may not constitute an investigation. The NPDB's definition of investigation excludes *a routine or general review of cases or a practitioner*. However, consultation with a medical staff attorney is always recommended in questionable cases. *See* 2018 Guidebook, p. E-37.

F. Question 25: Quality Improvement Plans May Be Reportable as Restrictions and May Qualify as Investigations

In the 2018 Guidebook, the NPDB recognizes that more hospitals are using quality improvement plans and clarifies when those plans may trigger NPDB reports.

Question 25:

Is a resignation while subject to a "quality improvement plan" a resignation while under investigation? A quality improvement plan might include a limit on the number of patients a physician can have in a hospital at a time or a requirement that all surgical cases be discussed with the physician's department chair in advance of surgery.

Answer:

Imposition of a quality improvement plan raises two issues with respect to reportability. First, a quality improvement plan may restrict a practitioner's clinical privileges if it imposes conditions on the practitioner's ability to treat or

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care for patients. If so, and if the restriction is the result of a professional review action, concerns the practitioner's professional competence or conduct, and is in place longer than 30 days, the plan may be reportable.

Second, if the quality improvement plan is not a restriction, it nonetheless may be considered an investigation so long as it meets the other requirements for an investigation. The reporting entity needs to determine whether the quality improvement plan is focused on one practitioner for competency concerns and whether such plans are a precursor to a professional review action. When making this determination, the entity should consider the language of the plan: Does it describe future disciplinary measures that may follow if the elements of the plan are not met? The entity also may consult its bylaws and policies, as well as standard practices, to decide whether the plan is the type of inquiry that leads to a professional review action. If the quality improvement plan meets the requirements of an investigation, then a resignation while under the plan would be reportable. 2018 Guidebook, p. E-51.

G.Question 46: Lapse of Privileges at End of 2-Year Appointment During an Investigation, But Before Hearing is Reportable

Hospitals already should be reporting to the NPDB practitioners who withdraw their applications for reappointment after the Medical Executive Committee recommends denial of the applications based on competence and conduct. The NPDB now requires that a report be made if a physician applies for reappointment and his/her privileges lapse while an adverse recommendation by the Medical Executive Committee is pending. It appears the report is required even though the practitioner submitted the application timely and the governing body has not made a decision.

Question 46:

Is a report required when clinical privileges lapse at the end of a 2-year appointment because there has been a recommendation by the Medical Executive Committee that the physician not be reappointed, but the physician's current 2-year appointment ends before a hearing can be held and final action taken by the hospital's governing body?

Answer:

Yes. A non-renewal while under investigation is reportable to the NPDB. In this scenario, the investigation is ongoing at the time the renewal lapses; therefore, the non-renewal is reportable as a resignation of privileges while under investigation. The practitioner's awareness that an investigation is being conducted is not a requirement for filing a report with the NPDB. 2018 Guidebook, pp. E-57-58.

There are a number of revisions to other parts of the 2018 Guidebook. The NPDB added a new section highlighting these updates under "Appendix C" at the end of the 2018 Guidebook.

Consultation with legal counsel is always recommended when a report may be required.

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Telemedicine: Considerations for Credentialing

Telehealth technology is rapidly expanding and consumers are increasingly adopting the delivery of telehealth services. Nevertheless, despite the increased use of telehealth technologies and services, hospitals face a number of significant legal and regulatory challenges when considering the provision of telehealth services.

Generally, the term "telehealth" is defined as the use of technology to deliver health care, health information or health education at a distance. Yet, the meaning of this term varies widely among the federal government, the states and other stakeholders using it. For example, Medicare does not define the term "telehealth" as a type of health care service, rather it is defined as a two-way, real-time, interactive communication between the Medicare beneficiary located at an "originating site" and the physician located at a "distant site" to facilitate delivery of health care services.[1] The Medicare rules explain that in order for Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary.[2] As a condition of payment, the patient must be present and participating in the telehealth visit.[3]

On the other hand, some states like Texas have separate, but similar, definitions for telehealth and telemedicine, including:

- "Telehealth service" means a health service, other than a telemedicine medical service, delivered by a health professional licensed, certified or otherwise entitled to practice in this state and acting within the scope of the health professional's license, certification or entitlement to a patient at a different physical location than the health professional using telecommunications or information technology.[4]

- "Telemedicine" and "telemedicine medical service" means a health care service delivered by a physician licensed in this state, or a health professional acting under the delegation and supervision of a physician licensed in this state, and acting within the scope of the physician's or health professional's license to a patient at a different physical location than the physician or health professional using telecommunications or information technology.[5]

Florida similarly defines telemedicine as "the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof."[6] Other states, such as California and Colorado, define telehealth as a mode of delivering health care services and public health via information and telecommunications systems to facilitate the assessment, diagnosis, consultation, treatment, education, care management and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site and in both instances, telehealth includes synchronous interactions and store and forward transfers.[7]

Although the definition of telehealth and telemedicine services may vary among states and federal agencies, there are three primary methods through which these services are provided in the hospital setting, including: (1) synchronous transmission, (2) asynchronous (store and forward) transmission, and (3) remote patient monitoring. The synchronous transmission method utilizes a live-video which allows for real-time, two-way interactions between persons (e.g., patients, caregivers or providers) and providers using audio-visual telecommunications technology. While this method originally enabled provider-to-provider communications, recent technology expansion now enables patients to connect directly to providers. Asynchronous transmission

[1] 42 U.S.C. §1395m(m); 42 C.F.R. §410.78.
[2] *Id.*
[3] Centers for Medicare & Medicaid Services, Medicare Benefit Policy Manual (Pub. 100-02), ch. 15, §270.
[4] Tex. Occ. Code §111.001.
[5] *Id.*
[6] Fla. Admin. Code 64B8-9.0141, 64B15-14.0081.
[7] Cal. Bus & Prof. Code §2290.5(a)(6); Col. Rev Stat § 10-16-123(4)(e).

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involves the storing of a patient's recorded health history (e.g., x-rays and photos) and forwarding that information through a secure electronic communications system. Generally, diagnostic information is recorded at the patient's site of care and transmitted to a specialist in another location. Remote patient monitoring allows for the transmission of a patient's clinical and other related data from an individual in one location to a provider in a different location.

While telehealth services may improve access to health care and improve outcomes because they may lead to a reduction of inpatient readmissions and emergency department admissions, there are several challenges that a hospital must resolve before implementing a telehealth program. These challenges include assessing state licensure requirements and provider credentialing.

States are generally tasked with managing the regulation of professionals, including health care providers, and implementing enforcement actions against such professionals for violating any professional rules or regulations. The challenge for telehealth providers is that every state requires a provider treating patients residing in the state to hold a valid and unrestricted license to practice medicine in the state. This typically necessitates a provider to have licenses in multiple states in order to be compliant with states' general rules.

In order to address this issue, some states, like Texas, offer providers the option to apply for a special telehealth or special purpose license. In Texas, while a person may not engage in the practice of medicine across state lines, the provider may apply for an out-of-state telemedicine license if the provider is (a) 21 years of age or older; (b) actively licensed to practice medicine in another state that is recognized by the Texas Medical Board for purposes of licensure, and not the recipient of a previous disciplinary action by any other state or jurisdiction; (c) not the subject of a pending investigation by a state medical board or another state or federal agency; and (d) passed the Texas Medical Jurisprudence Examination.[8] Texas' out-of-state telemedicine license is limited exclusively to the interpretation of diagnostic testing and reporting results to a physician fully licensed and located in Texas or for the follow-up of patients where the majority of patient care was rendered in another state. The following activities, however, are exempt from the requirements of Texas' out-of-state telemedicine license:

- Episodic consultation by a medical specialist located in another jurisdiction who provides such consultation services on request to a person licensed in Texas.
- Consultation services provided by a physician located in another jurisdiction to a medical school.
- Consultation services provided by a physician located in another jurisdiction to an institution.
- Informal consultations performed by a physician outside the context of a contractual relationship and on an irregular or infrequent basis without the expectation or exchange of direct or indirect compensation.
- Furnishing of medical assistance by a physician in case of an emergency or disaster if no charge is made for the medical assistance.
- Ordering of home health or hospice services for a Texas resident to be delivered by a home and community support services agency licensed by Texas, by the resident's treating physician who is located in another jurisdiction of a state having borders contiguous with the borders of Texas.[9]

Although several states have special purpose licenses for telehealth providers, other states have addressed the licensing issue by adopting the Interstate Medical Licensure Compact, which allows physicians to obtain a license to practice medicine in any Compact state through a simplified application process. Through the Interstate Medical Licensure Compact, state medical boards retain their licensing and disciplinary authority, but agree to share essential licensing information, creating an efficient process for licensure approval of willing and qualified physicians.[10] Some states rely on other means including, endorsement or reciprocity and bordering state exceptions.[11] A consultation exception may further allow out-of-state physicians who are duly licensed in another state to provide consultations to in-state physicians without requiring the consulting physician to be licensed in that state. Regardless of how

[8] 22 TAC §172.12.
[9] *Id.*
[10] States that have enacted legislation to expedite multi-state medical licensure include Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, Pennsylvania, South Dakota, Tennessee, Utah, Washington, West Virginia, Wisconsin and Wyoming.
[11] Washington D.C., Maryland, New York, and Virginia have adopted language that would facilitate licensure reciprocity from bordering states.

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the applicable state addresses the licensure issue, it is essential for the hospital to understand the licensing standards in both the state where the practitioner is located and the state where the patient is located to ensure that the practitioner is properly licensed.

Another potential organizational challenge to utilizing telehealth services, are the hospital's credentialing and privileging requirements. These may vary widely between facilities. Before a hospital permits a practitioner to provide services, the hospital must "credential" the provider by verifying the provider's education, training, and experience. After completing the credentialing process, the facility engages in the privileging process to assess the provider's competence in a specific area of care. Traditional credentialing for telehealth providers may be problematic because the hospital must engage in the credentialing and privileging processes each time a new physician in a distant site is used in a telehealth encounter.

Recognizing a streamlined credentialing process would be particularly beneficial in telemedicine, the Centers for Medicare and Medicaid Services ("CMS") enacted regulations to modify the credentialing and privileging processes for distant-site telemedicine providers.[12] The Joint Commission also implemented a distant-site credentialing approach for telemedicine providers.[13] Under these "credentialing by proxy" rules, if a physician is currently credentialed at Hospital A (the "distant-site hospital[14]), and subsequently applies for privileges to provide services via telemedicine only at Hospital B (the "originating-site hospital"[15]), the credentialing file and information developed by Hospital A may be used "by proxy" by Hospital B in connection with Hospital B's evaluation and decision to grant or deny the physician's telemedicine privileges. Although the credentialing by proxy process is optional, if a hospital agrees to accept credentialing and privileging by proxy, the originating-site hospital must enter into a written agreement with the distant-site hospital or distant-site telemedicine entity, which agreement must satisfy the following requirements:

- The distant-site hospital or distant site telemedicine entity uses a credentialing and privileging process that meets or exceeds the Medicare standards that hospitals have traditionally used.
- The telehealth provider must be privileged at the distant-site hospital or distant site telemedicine entity.
- The originating-site hospital must receive a current list of the telehealth provider's privileges from the distant-site hospital or distant site telemedicine entity.
- The telehealth provider is licensed to practice in the state where the originating-site hospital is located.
- The originating-site hospital periodically reviews the telehealth provider's performance and provides this information to the distant-site hospital or distant site telemedicine entity.
- The originating-site hospital must inform the distant-site hospital or distant site telemedicine entity of all adverse events and/or complaints regarding services provided by the telehealth provider.
- For contracts with distant site telemedicine entities only, the agreement must confirm that the distant site telemedicine entity is a contractor and provides services in a manner that permits the originating-site hospital to comply with all conditions of participation.[16]

The governing body of the originating-site hospital retains the ultimate authority over privileging decisions regarding telemedicine providers, regardless of whether the hospital credentialing process is conducted under the traditional approach or by proxy. As a result, the medical staff bylaws should include provisions for credentialing by proxy. Hospitals should therefore review their medical staff bylaws to determine whether the bylaws adequately address telehealth issues including, qualifications for medical staff membership (such as geographic proximity), the existence of a telehealth category for medical staff membership, telehealth privileges and credentialing by proxy.

By understanding the regulatory limitations and implementing appropriate processes for telemedicine providers, hospitals will be better positioned to deliver innovative services to patients who may not otherwise be physically present in their facility.

[12] 42 C.F.R. § 482.12, § 482.22(a)(3).
[13] LD.04.03.09, MS.13.01.01.
[14] CMS defines distant-site as the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunication system. 42 C.F.R. §410.78(a)(2).
[15] CMS defines originating-site as the location of an eligible Medicare beneficiary at the time the services being furnished via a telecommunication system occurs. 42 C.F.R. §410.78(a)(4).
[16] 42 C.F.R. §482.22.

Reduced Regulatory Burden for Hospitals and ASCs
Will Patient Care be Improved?


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On September 20, 2018, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule affecting the operation of hospitals and ambulatory surgery centers ("ASC"), among others.[1] The stated intent of the proposed rule is to increase the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care.[2] The public comment period concluded on November 19, 2018.

Among other subjects, the proposed rule has several important implications for hospitals, ASCs and their medical staffs relating to history and physical (H&P) requirements, system quality and infection control programs, ASC emergency transfers and facility emergency preparedness. Notably, the proposed rule includes the following:

- Allowing hospitals to establish medical staff policies that permit use of a pre-surgery/ pre-procedure assessment for hospital outpatient procedures, instead of a comprehensive medical H&P. A hospital would need to document the assessment in a patient's medical record, taking into consideration the patient's age, diagnoses, the type and number of surgeries and procedures scheduled to be performed and their respective levels of anesthesia, comorbidities, nationally recognized guidelines and standards of practice, and applicable state and local health and safety laws.[3]

- Allowing multi-hospital health care systems to adopt unified and integrated Quality Assessment and Performance Improvement ("QAPI") and Infection Control ("IC") programs for all of its member hospitals in accordance with state and local laws. Each separately certified hospital within the system would need to demonstrate that the unified QAPI and/or IC program takes into account each member hospital's unique circumstances; patient population and services; establishes and implements policies and procedures to ensure the needs and concerns of each of hospital were given due consideration; and has mechanisms in place to ensure that issues localized to particular hospitals were duly considered and addressed.[4]

- Removing the requirement that a hospital should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. Instead, CMS proposes to defer to state law regarding autopsy requirements.[5]

- Removing the requirement that ASCs either have a written transfer agreement with a hospital or ensuring that all physicians performing surgery in the ASC have admitting privileges at a local hospital. The emergency transfer of a patient from an ASC to a hospital would be governed instead by the receiving hospital's obligations under the Emergency Medical Treatment and Labor Act.[6]

- Removing the requirements that a physician or other qualified practitioner at an ASC conduct a comprehensive medical H&P on each patient not more than 30 days before the date of a scheduled surgery. The proposed rule would allow the operating physician and the ASC to determine which patients require more extensive testing and assessment prior to surgery. CMS would still

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[1]Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction, 83 Fed. Reg. 47686 (September 20, 2018) (to be codified at 42 C.F.R. Parts 403, 416, 418, 441, 460, 482, 483, 484, 486, 491, and 494).
[2]Medicare and Medicaid Programs; Proposed Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, CMS.gov (2018), https://www.cms.gov/newsroom/fact-sheets medicare-and-medicaid-programs-proposed-regulatory-provisions-promote-program-efficiency-0 (last visited Oct 26, 2018).
[3]83 Fed. Reg. 47686, 47700
[4]*Id.* at 47698
[5]*Id.* at 47701
[6]*Id.* at 47693

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require the operating physician to document any pre-existing medical conditions, appropriate test results, allergies to drugs and biologicals in the patient's medical record.[7]

- Allowing facilities to review their emergency preparedness program every two years, or more often at their own discretion, instead of annually.[8]

- Removing the requirement that the emergency preparedness plan include documentation of efforts to contact local, tribal, regional, state and federal emergency preparedness officials and a facility's participation in collaborative and cooperative planning efforts. This information is already contained in other regulations.[9]

- Allowing facilities to conduct training for emergency preparedness every two years after conducting initial training on their emergency program, instead of annually. Additionally, CMS proposes that facilities conduct training when their emergency plan is significantly updated.[10]

- Revising the emergency preparedness testing requirement for inpatient providers so that one of the two annually-required testing exercises may be an exercise of the facility's choice. While two annual tests are still required, one of those training sessions can be done through various means such as simulations, desk top exercises, workshops or other methods. The second training must still be a full scale community exercise.[11]

- Revising the emergency preparedness testing requirement for outpatient providers from two exercises to one testing exercise annually.[12]

These proposals are still in the early stages and may change after the public comment period. For most of these proposals, any reduction in the regulatory burden will depend on existing state laws. Additionally, there are significant questions regarding whether removing and/or revising certain regulations, such as those related to H&P requirements and transfer agreements between ASCs and hospitals, will actually improve patient care. The ability of a multi-hospital health care systems to unify their QAPI and IC programs, on the other hand, could lead to a greater exchange of information between member-hospitals; potentially resulting in improved patient care and outcomes. We will be monitoring future developments in this matter. If you would like to read the proposed rule, visit **www.gpo.gov/fdsys/pkg/FR-2018-09-20/pdf/2018-19599.pdf**

[7] *Id.* at 47695
[8] *Id.* at 47713
[9] *Id.* at 47714
[10] *Id.*
[11] *Id.*
[12] *Id.*

Erin L. Muellenberg
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What Duty is Owed by the Volunteer Physician?

How California is distinguishing the importance of Ethics and Medical Staff Care Committees

A three-judge court of appeal panel for the Fourth District Court of Appeal in California, in *Alexander v. Scripps Memorial Hospital La Jolla*, 23 Cal.App.5th 206 (2018) affirmed the dismissal of a suit, that accused the hospital and physicians of failing to provide life-saving measures to a terminally ill cancer patient with an advance directive that requested life saving measures. Even though plaintiffs' decedent had specified in her Health Care Advance Directive that she wanted all possible steps to be taken to prolong her life, the court found the doctors were not required to give her care that they reasonably believed would be medically ineffective or would not offer the patient any significant benefit.

In this case, the decedent was suffering from terminal pancreatic cancer that had metastasized into her ribs. One treating physician communicated to family that maintaining full code status, including CPR and similar measures, would cause the terminally ill patient to suffer additional harm and suffering. This physician also initiated steps to involve the Appropriate Care Committee.

The Appropriate Care Committee, comprised of volunteer physicians, provided recommendations as to whether certain treatment was appropriate for a patient. After

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reviewing records and observing the patient, the Appropriate Care Committee recommended against advanced life support measures, including CPR. After the consultation, members of the treating team determined life-saving measures such as CPR, artificial nutrition or hydration would be ineffective and cause the patient additional pain and suffering.

The next day the patient died. No advanced life support measures were used.

The appellate court determined that members of the Appropriate Care Committee did not treat the patient. Instead, they reviewed records and observed the patient to provide recommendations that the treating physicians could accept or reject. The appellate court ruled, under these circumstances, members of the Appropriate Care Committee did not have a physician-patient relationship sufficient to impose upon them a duty of care.

This appellate decision is important because it helps clarify the role of the Appropriate Care Committee, and those like it and reinforces their immunity from liability. The function of these committees is to provide guidance to treating physicians on a volunteer basis. This independent review can assist treating physicians in making the best decisions for patient care and avoiding use of medically ineffective care. Physicians who volunteer on medical staff appropriate case or ethics committees do not hold the same duty of care as a physician with a physician-patient relationship. Instead, these volunteer physicians provide a consultative role to the patient's physician to assist in his/her decision making.

The appellate court also rejected the plaintiffs' claims that the health care providers violated California's Health Care Decisions Law, which protects individuals' rights to control their own health care decisions. Rather, the court found the doctors were entitled to immunity when acting in good faith. The appellate court discussed that the physicians' decisions to withhold treatment requested in the decedent's advance health care directive was consistent not only with ethical duties, but also with the Health Care Decisions Law. The court held that evidence showing the defendants' actions were directed at providing only medically beneficial and effective care, without further harming or causing further pain to the patient, was the equivalent of acting in good faith.

This case should reassure Medical Staff members who participate on Ethics or similar Medical Staff Committees and assist physicians with difficult decisions that may be controversial with families.

If you would like to read the court of appeal's ruling in this matter, it can be found at: **https://law.justia.com/cases/california/court-of-appeal/2018/d071001.html**

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Associate

Texas Trial Court Enters $6.3 Million Judgment for Doctor Against Hospital for Defamation, Appeal Pending

It is rare that physicians succeed on claims against hospitals in Texas. Recently, however, the First Court of Appeals heard oral argument on cross appeals, where a trial court, based on a jury verdict, awarded a doctor $6.3 million dollars on his defamation and business disparagement claims. *Miguel A. Gomez, III, M.D. and Miguel A. Gomez, M.D., P.A. v. Memorial Hermann Hospital System, et al.*, No. 2012-53962 (333rd Dist. Ct. Tex. filed Sept. 17, 2012) (hereinafter the "Gomez Case").

In 1998, Dr. Miguel A. Gomez ("Gomez"), a cardio-thoracic and general surgeon with experience in robotic-assisted surgical procedures,[1] Gomez obtained privileges and medical staff membership at Memorial City Hospital (the "Hospital"). The hospital is owned and operated by Memorial Hermann Hospital System ("Memorial").[2]

In 2009, the Methodist Health System announced the opening of a new hospital, Houston Methodist West ("Methodist West"), near the Hospital.[3] According to Gomez, he intended on splitting his practice between Methodist West and the Hospital because he was unhappy with the care his patients were receiving at the Hospital.[4] Gomez contends that in 2009, Hospital representatives joined in a scheme to destroy his reputation and ability to practice medicine in the West Houston and Katy communities when they learned Gomez intended to split his practice. He claims the Hospital's motive was to discourage other doctors from referring patients and cases to Gomez and prevent Gomez from diverting potential revenue away from the Hospital and to Methodist West.[5]

According to Gomez, Byron Auzenne ("Auzenne") (the Hospital's Heart and Vascular Service Line Leader), at the direction of the Hospital's Chief Executive Officer Keith Alexander, began to review the Society of Thoracic Surgeons ("STS") cardiovascular surgery mortality data.[6] Once the review of STS data began, the Hospital believed the overall mortality rate from cardiovascular surgeries was too high.[7] This led the Hospital to use a statistical model of individual cardiovascular surgeon mortality rates to evaluate surgeon quality, which reportedly showed that Gomez had a higher than average mortality rate.[8] Gomez alleges that the individual surgeon mortality rate generated by the Hospital was misleading and statistically flawed.[9]

Gomez claims the Hospital's administration set up an emergency meeting and presented Gomez with the option of either immediately suspending his practice or agreeing to active interventional monitoring under the Hospital's supervision.[10] After this meeting, the cardiovascular surgeons, including Gomez, underwent peer review, which resulted in no adverse action against any of the surgeons' clinical privileges.[11]

Gomez contends that after the peer review process, the Hospital's administration and staff began a whisper campaign to spread false information in order to discredit him in the medical community.[12] At trial, Gomez presented two statements to the jury to support his defamation and business disparagement claims.[13]

Cyndi Pena, a physician liaison for Methodist West who formerly held the same position at the Hospital, testified that Jennifer Todd ("Todd"), a physician liaison for the Hospital, reached out to Ms. Pena because Todd heard that Gomez was going to practice at Methodist West.[14] Ms. Pena testified that Todd told her to "[b]e careful," because "there's things being said here, and they're pertaining to the bad quality, mortality rate. There was – I heard bad quality, high mortality rates, unnecessary surgeries."[15]

Plaintiffs Miguel A. Gomez and Miguel A. Gomez, P.A. (collectively "Gomez") filed their Fifth and last Amended Petition ("Petition") on February 1, 2016. The current defendants are Memorial Hermann Health System ("Memorial") and Memorial Hermann Physician Network. For the purposes of summarizing the alleged facts, the paper relies on Gomez's Petition ("Gomez Pet."), the Amended Appellate Brief submitted by Gomez on May 21, 2018 ("Gomez Brief"), and the Appellate Brief submitted by Memorial ("Memorial Brief").

[1] *Gomez Pet. ¶ 5.2.*
[2] *Gomez Brief P. 4.*
[3] *Gomez Brief P. 6-7.*
[4] *Gomez Brief P. 8.*
[5] *Gomez Pet. ¶ 9.4. Gomez alleges that, on or about 2009, the Hospital's previous CEO told another physician if she moved her practice to Methodist West, she would be "committing political suicide." Gomez also claims the former CEO told the physician her practice "could be in jeopardy" if she did not refer her patients to Memorial-affiliated oncologists and imaging services. He further alleges, that at that time, the Hospital began holding town hall meetings in order to gain information about who wanted to leave the Hospital. Gomez Brief P. 11.*
[6] *Gomez Brief P. 12.*
[7] *Memorial Brief P. 4.*
[8] *Gomez Brief P. 14.*
[9] *Gomez Brief P. 14-17.*
[10] Gomez Pet. ¶ 5.9.
[11] *Id.*
[12] Gomez Brief P.23-24.
[13] Gomez Brief P. 23-30.
[14] Gomez Brief P. 26.
[15] Gomez Brief P. 26-27.

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Gomez testified that on November 1, 2011, at a Cardiovascular and Thoracic physician network meeting, the allegedly misleading mortality rate data was presented.[16] After the meeting concluded, Gomez approached Auzenne and asked him why the misleading statistical data was being presented again.[17] Gomez testified that Auzenne stated, "he had spoken to CEO Keith Alexander and they had discussed it" and "they felt that the data needed to be shared, that we needed to be a transparent organization, that this was a safety issue."[18] Further, Gomez testified Auzenne told him that "they were going to share [the data]. They felt compelled to share the data with all the doctors."[19] Auzenne denies making this statement.[20] These two alleged statements by Auzenne and Todd formed the basis of Gomez's claims for business disparagement and defamation at trial.

Gomez resigned his privileges at the Hospital in May of 2012, and took his practice to Methodist West, where he had already obtained privileges.[21] Significantly, there is no evidence or allegations that the Hospital suspended Gomez, instituted proctoring upon Gomez's privileges, or made any report to the National Practitioner Data Bank concerning his privileges.

Gomez filed suit on September 17, 2012, against Memorial for business disparagement, defamation, restraint of trade and tortious interference with prospective relations. Memorial denied the allegations in Gomez's Petition and raised numerous affirmative defenses,[22] including immunity under the Health Care Quality Improvement Act[23] and the Texas Occupations Code.[24]

In 2015, the case produced a Supreme Court of Texas opinion regarding the anticompetitive exception to the medical peer review privilege. The Supreme Court found that such exception applied to certain peer review privileged documents, because Gomez had successfully pled and provided some evidence of a restraint of trade claim.[25] As such, Memorial was required to produce privileged documents and materials relevant to Gomez's anticompetitive claim.[26]

The jury returned its verdict on March 29, 2017, only finding in favor of Gomez on the business disparagement and defamation claims for the two statements allegedly made by Auzenne and Todd and awarded damages in the sum of $6.3 million dollars.[27] There was no finding that the STS mortality data constituted defamation or that any comments made in the original meeting by administration or in subsequent medical peer review meetings were actionable. Memorial appealed, Gomez cross-appealed, and oral argument was held on October 30, 2018 before the First Court of Appeals.[28]

The primary issues on appeal are: (1) whether Auzenne's statement to Gomez meets the requirement of publication to a third-party for defamation and business disparagement;[29] (2) whether the statement by Todd actually caused Gomez's alleged damages;[30] (3) whether the Todd and Auzenne statements were protected by a qualified privilege and therefore not defamatory;[31] and (4) whether the trial court erred by only allowing the jury to answer questions regarding Gomez's tortious interference claim if the jury first found in favor of Gomez on his restraint of trade claim.[32]

We will provide an update on this matter when the First Court of Appeals renders its decision.

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[16]Gomez Brief P. 30-31.
[17]Gomez Brief P. 32.
[18]*Id.*
[19]*Id.*
[20]Memorial Brief P. 7.
[21]Memorial Brief, P. 7.
[22]Defendants' Second Amended Answer and Affirmative Defenses.
[23]42 U.S.C. Section 11101 *et.seq.*
[24]Tex. Occ. Code, Section 160.010
[25]*Id.*
[26]*Id.* at 715-16.
[27]Court's Charge executed March 29, 2017.
[28]*Memorial Hermann Health System v. Miguel A. Gomez, M.D., and Miguel A. Gomez, M.D., P.A.*, No. 01-17-00632-CV (1st Ct. of App. Filed Aug. 10, 2017)
[29]Memorial Brief, P. 15.
[30]*Id.* at 27.
[31]*Id.* at 34-37.
[32]Gomez Brief, P.35-36

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