LHA IMPACT LAWBRIEF

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Notices:

- **HOSPPAC REMINDER:** The year-end deadline of Dec. 15 is quickly approaching to contribute to HOSPPAC. HOSPPAC met its federal AHAPAC goal in October, so 100% of all contributions received now will be used for state campaign purposes. We need your help to reach our goal for 2016, so please contribute online today.

- **ARTICLE SUBMISSION:** The LHA Society of Hospital Attorneys encourages its members to submit articles on topics of interest. Writing an article that is published in *Lawbrief* is a great way to promote your name in the healthcare community and advertise your knowledge. If you have written an article and would like to have it considered for publication in *Lawbrief*, please email it in Word format (no PDFs please) to Angela Lockhart at alockhart@lhaonline.org.

Headlines:

Articles:

***Billeaudeau* and Beyond: Preparing for Negligent Credentialing Litigation**

By: Judy Giorlando, Carroll Devillier, and Dani Borel

On Oct. 19, 2016, the Louisiana Supreme Court rendered a decision that alters the landscape of medical malpractice litigation for healthcare providers. In *Billeaudeau v. Opelousas Gen. Hosp. Auth*., 2016-0846 (La. 10/19/16), the Court held that the Plaintiffs' claim for negligent credentialing against a hospital did not fall within the purview of the Louisiana Medical Malpractice Act (LMMA). Therefore, the claim for negligent credentialing was not subject to review by a medical review panel nor the limitations of liability under the LMMA.

The *Billeaudeau* matter arose initially out of treatment received in the Emergency Department at Opelousas General Hospital (OGH) by Dr. Zavala, an independent contractor of OGH. The Billeaudeaus collectively filed suit against OGH asserting that OGH was negligent for the following reasons:

a. Failure to develop and/or implement adequate policies and procedures to competently address stroke and/or administration of tPA;

b. Failure to distribute its written stroke and/or tPA protocol to Dr. Kondilo Skirlis-Zavala, the treating physician in the hospital's emergency department;

c. Failure to ensure that Dr. Zavala had reviewed and accepted the hospital's written stroke and/or tPA protocol;

d. Failure to supervise Dr. Zavala, a physician working in Opelousas General's emergency department; and

e. Negligent credentialing of Dr. Zavala.

Thus, in addition to the complaints about the care she received, the Billeaudeaus alleged "negligent credentialing." Specifically, the Plaintiffs asserted that Dr. Zavala was not qualified to be credentialed by OGH under the OGH's credentials policies.

The Billeaudeaus filed a motion for partial summary judgment "asking the District Court to declare their claim against OGH for negligent credentialing was not subject to the terms of the LMMA, including the cap on damages found in La. Rev. Stat. § 40:1231.2(B)(1)." *Id.* The dispute centered around the LMMA's definition of "malpractice," found at La. R.S. 40:1299.41(A)(8), and whether negligent credentialing was included. The Plaintiffs argued their negligent credentialing claim arose from a breach of Louisiana Revised Statute 40:2114, which obligates hospitals to establish and regulate staff membership and clinical privileges. §2114, they argued, was housed by a statutory regime separate from the LMMA, and thus not susceptible to the limitations of the LMMA. OGH opposed the Plaintiffs' motion and argument, asserting that the suit at hand should not be construed more broadly than a medical malpractice claim. The trial court granted the Plaintiffs' motion for summary judgment, a decision that was affirmed by the Louisiana Third Circuit Court of Appeal.

The Louisiana Supreme Court's holding—agreeing with the Plaintiffs' position—was ultimately rooted in the application of the *Coleman v. Deno* factors, six factors that help courts determine whether certain conduct by a qualified healthcare provider constitutes "malpractice" under the LMMA. *See* 2001-1517 (La. 1/25/02), 813 So. 2d 303, 307. Importantly, in assessing the six factors, the Court found that the decision to hire this physician was *administrative* and not directly related to patient treatment or dereliction of professional skill. Also, expert medical evidence would not be necessary to establish the alleged wrong. Based on these findings, the Plaintiffs' negligent credentialing claim was deemed not subjected to the limitation on liability under the LMMA and was allowed to remain before the trial court while the corresponding claims of medical malpractice were pending before the medical review panel.

Interestingly, the Court did not discuss the legislative history of the LMMA in their analysis, as was discussed in detail by the trial court. Also, the Court did not analyze prior negligent credentialing decisions, such as the *Plaisance v. Our Lady of Lourdes Reg'l Med. Ctr., Inc.* decision where it was held that the plaintiffs' "negligent credentialing" claim fell within the purview of the LMMA after the court conducted an analysis of the *Coleman* factors. *See* 2010-348 (La. App. 3 Cir. 10/6/10), 47 So. 3d 17, 22, *writ denied*, 2010-2520 (La. 1/14/11), 52 So. 3d 904. Rather, the Court dismissed those decisions are distinguishable based on their "mixed allegations of negligent credentialing and supervision or strictly negligent supervision claims," the latter of which falls under the LMMA.

Healthcare providers relying upon the LMMA to protect them from uncapped liability on all medical malpractice claims need to consider how this decision will impact their healthcare operations and liability exposure. First, all credentialing policies and practices for all levels of providers should be reviewed and audited for compliance. Second, healthcare providers should be alert to the impact the litigation discovery procedures will have on its existing peer review process. Careful consideration of these credentialing issues can best ensure that the important protections provided in Louisiana's peer review statute La. Rev. Stat. § 13:3715.3 are properly maintained. And last, but certainly not least, healthcare providers should determine whether they have adequate liability coverage in place for these uncapped claims and for all of the participants in the credentialing process.

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Final Rules on Reimbursement for Off-Campus Provider-Based Departments

By: Michael Schulze, Isabel Bonilla-Mathé

On Nov. 2, 2015, Congress surprised providers with the passage of Section 603 of the Bipartisan Budget Act of 2015 (the "Act"), which eliminates Medicare Outpatient Prospective Payment System (OPPS) reimbursement for off-campus outpatient provider-based departments (off-campus PBEs) established post enactment of the new law. The Act discontinued the favorable reimbursement received by off-campus PBEs, providing instead for site neutral payments. Beginning Jan. 1, 2017, this "site neutral" Medicare reimbursement will apply to any off-campus PBE that was not billing as an off-campus PBE prior to Nov. 2, 2015. Off-campus PBEs in existence prior to Nov. 2, 2015, are "grandfathered" and are exempted from the new site neutrality payments.

On July 6, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a set of proposed rules implementing the Act. A few months later, on Nov. 1, 2016, the much awaited final rules were published, along with an interim final rule with comment period to establish a payment mechanism under the Medicare Physician Fee Schedule (MPFS) for non-exempt PBEs. The following provides a brief overview of some of the main provisions of the final rules. However, there is no doubt that compliance guidance for off-campus PBEs will evolve as these regulatory changes will require additional rulemaking and further guidance from CMS.

Grandfathered Status Based on Date of Service: The final rule reiterated that provider-based off-campus outpatient clinics established prior to Nov. 2, 2015, will continue to receive OPPS reimbursement, whereas clinics established after that date will receive site neutral payment. In the proposed rules, CMS stated that only off-campus PBEs that had billed items and services under OPPS prior to Nov. 2, 2015 would be grandfathered. In the final rules, CMS adopted a more flexible approach by grandfathering off-campus PBEs that had *furnished* items or services with dates of service prior to Nov. 2, 2015 and timely billed for those services under OPPS.

No Under Development Exception: CMS declined to create an exception that would grandfather off-campus PBEs that were under development and permit them to that seek OPPS reimbursement, since such facilities would not have been *furnishing* services prior to Nov. 2, 2015. As CMS had indicated in the proposed rules, CMS again noted in the final rule that it did not believe the Act granted the agency with the authority to create an exception for off-campus PBEs that may have been under development.

New Rule Does NOT Apply to Services Furnished in an Emergency Department: Contrastingly, emergency departments, which are expressly exempted in the Act, are not subject to the prohibition on OPPS payment. In the final rule, CMS interpreted the express exemption as providing that that all services rendered in an emergency department setting, even if not an "emergency service," will receive OPPS reimbursement.

New Rule Does NOT Apply to Critical Access Hospital PBEs: CMS's final rules do not impact payments to critical access hospitals (CAHs) operating off-campus PBEs. Section 603 of the Act passed Nov. 2, 2015 ONLY affects payments made under Section 1833(t) of the Social Security Act (SSA). Because CAHs are paid for outpatient services under Section 1834(g) of the SSA, the exclusion does not apply to CAH off-campus PBEs. Accordingly, CAHs can continue to establish off-campus departments on or after Nov. 2, 2015 as long as the new CAH off-campus PBEs comply with any CAH related requirements, including distance from the CAH and from other hospitals and CAHs as required by 42 C.F.R. § 485.610(e).

New Rule MAY not apply to Rural Health Clinics: The final rules published by CMS did not address provider-based rural health clinics (RHC). Like CAHs, RHCs are not subject to the Section 603 exclusion from OPPS. RHCs are separately enrolled and certified providers under the Medicare program. Thus, like CAHs, RHCs are not paid under the OPPS, and Section 603 and the final rules implementing the same, should not affect the payment for RHC services. However, it should be noted that CMS did not clarify how it would treat hospital-based outpatient services provided by RHCs.

Additional Services Not Prohibited: Yet another issue addressed by the final rules was how CMS was going to treat service expansion by grandfathered off-campus PBEs. In the proposed rules, CMS took the position that off-campus PBEs would be exempted only for the types of items and services included in any of the 19 "clinical families" the provider had been providing prior to Nov. 2, 2015. In the final rule, CMS declined to implement the proposed rule, agreeing with commentators that it would be too complex to administer. Instead, an excepted off-campus PBE "will receive payments under the OPPS for all billed items and services, regardless of whether it furnished such items and services prior to the date of enactment." CMS stated it will monitor billing data and may consider a mechanism to limit service expansion, either by placing a limitation on volume, as suggested by commentators, or a limitation on lines of service, as was contemplated in the proposed rule.

Expanding or Moving Location IS Prohibited – Normally: While expanding service lines may not jeopardize the grandfathered status of an entity's off-campus PBE, relocating or expanding the size of the off-campus PBE location will, absent extraordinary circumstances. CMS stated in the final rule that grandfathered off-campus PBEs will lose their excepted status if they expand or relocate from the physical address and suite number listed on the locations' provider enrollment form. CMS will only permit excepted locations to relocate for extraordinary circumstances. Although the final rules provided examples of "extraordinary circumstances," such as natural disasters, or significant public health and safety issues, CMS declined to provide an exhaustive list, preferring to evaluate exceptions to the relocation prohibition on a case-by-case basis.

Change of Ownership May Jeopardize Grandfathered Status: If a hospital sells one of its off-campus PBE locations, the grandfathered status of that location will not transfer to the new provider. Hospitals considering a change of ownership (CHOW) should be aware that the potential sale could cause the hospital to lose grandfathered status of its off-campus PBEs. This can be avoided, however, if the new owner accepts the hospital's provider agreement. This can also be avoided if the purchaser avoids a CHOW altogether by acquiring the membership units or shares in the entity that owns the hospital.

CMS to Cut Payments to Non-Grandfathered PBEs: While CMS has yet to figure out the logistics and payment mechanisms necessary to implement the payment system for non-grandfathered PBEs, CMS did provide some clues in the final rule. CMS stated that starting Jan. 1, 2017, payments would be processed through the MPFS and set at "50 percent of the OPPS rate for each nonexcepted item or service with some exceptions." CMS admitted that it had no mechanism to pay providers in 2017 for nonexcepted services and solicited public comments regarding the proposed system. CMS stated that providers will be able to bill nonexcepted services on an institutional claim with a "PN" modifier, which will trigger payment under the new MPFS payment rates. Furthermore, CMS will pay hospitals directly for these nonexcepted services, as a means of addressing commentator's concerns regarding issues such as "incident to" billing, and the application of the fraud and abuse laws.

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