LHA IMPACT LAWBRIEF

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Louisiana Hospital Association

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Notices:

- **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 get your name out 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.

- **CALL FOR HEALTH LAW SYMPOSIUM SPEAKERS AND TOPICS:** Have you thought of sharing your experience and expertise? Have you heard a good speaker? We are interested in hearing from you on what speakers you would like to hear on a variety of current trending topics that impact the way healthcare is practiced. Please email Angela Lockhart at alockhart@lhaonline.org to recommend topics and speakers. The LHA's Health Law Symposium is the most comprehensive program for healthcare law practitioners featuring materials on important health law topics from leading experts and is currently being planned for October 2016 (dates are still pending).

Headlines:

Articles:

Legislative Changes Result in Dispute Over Sales Tax on Medical Device Purchases

By: Andrew Kolb

A significant sales tax issue is brewing for Louisiana healthcare providers with regard to medical devices. Article 7, Section 2.2 of the Louisiana Constitution specifically exempts prescription drugs from sales and use taxes imposed by the State. Louisiana Revised Statute 47:301(20) in turn defines "drugs" for tax purposes as "all pharmaceuticals *and medical devices* which are prescribed for use in the treatment of any medical disease."

Despite the fact that the constitutional sales tax exemption for pharmaceuticals and medical devices is still in effect, the Louisiana Department of Revenue (LDR) is taking the position that medical device purchases are now subject to state sales tax by virtue of Acts 25 and 26 of the First Special Session of the 2016 Louisiana Legislature. The LDR has provided a table that reflects the LDR's position that the applicable state sales tax rate on medical devices is 5% for the period from April 1, 2016 through June 30, 2016, and then 3% from July 1, 2016 through June 30, 2018.

According to the LDR, these sales tax rates now apply to purchases of medical devices such as pacemakers and heart catheters, as well as any other medical device prescribed for use in the treatment of any medical disease that does not fall into the specifically defined categories of orthotic or prosthetic devices. The sales tax exemptions for orthotic and prosthetic devices were specifically reinstated in the sales tax "cleanup" bill during the Second Special Session of the 2016 Louisiana Legislature. *See* Act No. 12 of the 2016 Second Extraordinary Session of Louisiana Legislature. Act 12 did not, however, address the exemption for medical devices in general. The medical device exemption still exists via Article 7, Section 2.2 of the Louisiana Constitution.

This leaves an important dispute between healthcare providers and the LDR as to the taxability of purchases of medical devices. A number of Louisiana healthcare providers have already begun remitting sales taxes on medical device purchases under protest and are filing lawsuits to have the courts determine whether the purchases are exempt from sales tax under the Louisiana Constitution. In order to pay under protest, taxes must be remitted with a protest letter to the LDR by the 20th of the month following the month in which the sales and/or use taxes on medical device purchases were incurred. A lawsuit must then be filed either with the Louisiana Board of Tax Appeals or state district court within thirty (30) days of the protest payment. If sales taxes on medical device purchases are paid without protest, it may not be possible for taxpayers to later recoup taxes paid, even if the courts ultimately rule in favor of the healthcare providers. Further, if the sales taxes go unpaid, there is the potential for penalties and interest to be assessed against the taxpayer while the issue is litigated.

If you are interested in protecting your organization's right to recoup sales taxes on medical devices, you should consult further with a tax or legal professional.

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Department of Justice Doubles Healthcare Civil Fraud Penalties Starting August 1, 2016

By Michael R. Schulze

The U.S. Department of Justice (DOJ) published an interim final rule on June 30 that dramatically increased potential civil penalties under the Civil False Claims Act and the Federal Anti-Kickback Statute. Currently, violations of the statutes include potential civil fines that range from a minimum of $5,500 to a maximum of $11,000 per claim. The new rule, effective August 1, 2016, implements the following increases per claim:

False Claims Act: $5,500 (min.) increased to $10,781
$11,000 (max.) increased to $21,563

Anti-Kickback Statute (civil): $11,000 increased to $21,563

Considering the volume of claims hospitals and other providers file on a daily basis, providers have become increasingly concerned that alleged violations of the statutes will subject the provider to massive potential penalties that the provider could never repay. The large potential fines are one of the reasons very few providers even attempt to defend themselves all the way to trial. Rather most providers seek to negotiate the best possible settlement in order to avoid being bankrupted.

The DOJ's final rule virtually doubling the possible civil fines will undoubtedly have a devastating impact on providers. Consider the example of the Tuomey Healthcare System in South Carolina. Tuomey was accused of violating the Federal Stark Statute with several of its financial relationships with physicians. The case became a grand cautionary tale, because the court reached a verdict that included a $237 million judgment against the hospital.

The jury found that Tuomey committed 21,730 separate violations of the False Claims Act by knowingly submitting 21,730 claims to Medicare in violation of the Stark statute. These claims resulted in actual damages of $39,313,065, which was trebled under the statute for a total of $117,939,195 in compensatory damages. The district court applied the statutory minimum of $5,500 to each of the 21,730 false claims and fined Tuomey an additional $119,515,000. The combination of actual, compensatory damages and the ***minimum*** civil penalty resulted in a $237,454,195 verdict against the Hospital. Had the new interim final rule been in effect, Tuomey's minimum civil penalty would have jumped from a mere $119,515,000 to $234,271,130.

One of the federal judges in the Tuomey case issued a concurring opinion upholding the verdict and the damages award, but drew attention to the often devastating impact the enforcement of healthcare statutes and regulations can have on providers and the public they serve by lamenting about "the troubling picture this case paints: an impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area." By almost doubling the size of the potential civil fines, the federal government has dramatically increased the pressure hospitals and other providers will face when starring down allegations of potential regulatory violations.

More than ever, hospitals must be proactive and diligent in its compliance efforts to avoid, detect and correct mistakes or behavior that violates the "impenetrably complex" set of healthcare laws and regulations. The hospital's proactive and diligent efforts should be organized and guided by a compliance plan that is fully integrated into the hospital's daily operations and that has been reviewed and updated by experienced health care regulatory counsel.

Michael Schulze is a managing member of Sullivan Stolier, LLC, dedicated to the regulatory compliance, transactional and business needs of healthcare providers. He can be reached by phone at (337) 233-6210 or by email at mschulze@sullivanstolier.com.

Final Rule Standardizes and Clarifies Appeals and Grievances Procedures for Medicaid Managed Care Plans

By: Dani Borel

On May 6, 2016, the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) issued a final rule in the federal register, 81 FR 27498, focusing on various aspects of Medicaid managed care plans. Under Medicaid managed care arrangements, beneficiaries receive all or part of their Medicaid services from health care providers that are paid by an organization that is under contract with the state. The managed care plan receives monthly payments from the state and is responsible for "managing" the funds received to pay beneficiaries' Medicaid claims. Over time, the Medicaid managed care model has grown in popularity, with 73.5% of Medicaid beneficiaries accessing their Medicaid benefits through managed care organizations ("MCOs") as of July 2013.

The final rule is intended to "modernize[] the Medicaid managed care regulatory structure to facilitate and support delivery system reform initiatives to improve health care outcomes and the beneficiary experience while effectively managing costs." Also, the rule aims to "strengthen the quality of care provided to Medicaid beneficiaries . . ." Finally, as is always a goal when discussing public funds, the rule ensures accountability and appropriate stewardship of the funds.

One of the specific areas addressed by the final rule, and the subject of this article herein, is the appeal and grievance procedures utilized by Medicaid managed care plans. Currently, the appeal and grievance procedures of Medicaid managed care entities are regulated by 42 C.F.R. 438, subpart F. These amendments were prompted by CMS's concern that "the different appeal and grievance processes for the respective programs and health coverage cause: (1) Confusion for beneficiaries who are transitioning between private health care coverage or [Medicare Advantage] coverage and Medicaid managed care; and (2) inefficiencies for health insurance issuers that participate in both the public and private sector." Thus, the revisions are

intended to "better align appeal and grievance procedures across these areas to provide consumers with a more manageable and consumer friendly appeals process . . ." Louisiana providers' experiences with Louisiana Medicaid managed care entities are testaments to the need for these changes.

Enrollees, Providers with Written Consent, and Authorized Representatives Can Request Appeals

While CMS considered removing the requirement that providers obtain written consent from an enrollee before requesting an appeal on the enrollee's behalf, CMS was persuaded by commenters to forego this change. Specifically, CMS was persuaded by the potential financial liability of enrollees for services received during an appeal taken on their behalf by the provider. CMS was not persuaded, however, to expand the list of authorized representatives who can request an appeal on behalf of the enrollee to include legal representatives, attorneys, enrollee advocates, and legal guardians. While CMS acknowledged these representatives may effectively serve as authorized representatives, CMS chose to allow the states to retain the right to define who is recognized as an authorized representative of an enrollee. Louisiana recognizes an appeal filed by either the member/enrollee or "a representative of his/her choice," which can include "a network provider acting on behalf of the member and with the member's consent." 50 La. Admin. Code Pt I, 3705. For the sake of this article, the term "enrollee" includes members, providers, and authorized representatives.

The Difference in an Appeal and a Grievance Focuses on the Adverse Benefit Determination

Patients, providers, and health plans often used the terms "appeal" and "grievance" interchangeably. Yet, the "Grievance and Appeal System" outlined by subpart F of 438 treats these two concepts differently. The definitions found in §438.400 provide a starting point for grievance and appeals regulations. This section defines both "appeal" and "grievance," highlighting the legal difference in those terms.

An appeal is a request for the MCO, Pre-paid Inpatient Health Plans ("PIHPs"), or Pre-paid Ambulatory Health Plans ("PAHPs") to review an adverse benefit determination issued by the MCO, PIHP, or PAHP. An adverse benefit determination is defined to encompass an assortment of disputes between the enrollee and entity, including the reduction, suspension, or termination of a previously authorized service and the denial in whole or part of payment for a service.

In contrast, a grievance is any expression of dissatisfaction about a matter other than an adverse benefit determination. A grievance can be filed to address quality of care or services provided, the rudeness of an employee or provider, and disputes regarding proposed extension of time for the MCO, PIHP, or PAHP to make an authorization decision. While some processes for appeals and grievances are the same, some aspects—such as timeframes—differ.

Standardization of Two Levels of Review

Notably, the appeal process is now standardized to include two levels of review: 1) review by the MCO, PIHP, or PAHP, and 2) a state fair hearing. The first step to standardizing the two-level review was ensuring a review by the managed care plans. A revision to the definition of "appeal" at §438.400(b) now provides that an appeal is a review by the MCO, PIHP, or PAHP, rather than merely a "request for a review" as before. This revision will guarantee an additional review where previously the additional review could be declined by the MCO, PIHP, or PAHP. Going forward, Louisiana MCOs, PIHPs, or PAHPs cannot decline to review the previous finding of the entity, but *must* conduct an appeal.

A second change to the proceeding of the appeal impacts the enrollee's ability to initially seek a state fair hearing. Under the new rule, enrollees must exhaust their single level appeal with the MCO, PIHP, or PAHP, then the enrollee is given the opportunity to seek a state fair hearing. In Louisiana, our state fair hearing is handled by the Division of Administration and follows the rules of Louisiana Administrative Procedure Act.

In addition, CMS amended subpart F to be applicable to Pre-paid Ambulatory Health Plans ("PAHPs"), expanding the regulation to govern PAHPs, MCOs, and PIHPs. This addition of PAHPs now prevents PAHP enrollees from immediately seeking a state fair hearing without undergoing an initial review with the PAHP, as was a practice previously. However, Non-Emergency Medical Transportation PAHPs remain excluded.

Finally, CMS also reiterated the obligation of states to monitor appeals and grievances within their respective programs per §438.66.

Clarity Provided in Timeframes for Appeals and Grievances

CMS addressed the Achilles heel of any appeals process: the deadlines. To provide clarity, all deadlines are now calculated by "calendar" days, as opposed to "business" days or any other method. For example, if the deadline is three days from a Friday, the deadline would be the Monday (which is three calendar days from Friday), not the Wednesday (which is three business days from Friday). As always, the importance of immediately calendaring all appeal deadlines cannot be overstated.

Previously, states could set the adverse benefit determination appeal request timeframe between 20-90 days. Now, the filing of appeal requests must be accomplished within 60 calendar days from an adverse benefit determination notice and a grievance can be filed at any time. Interestingly, CMS expects adverse determination notices to be mailed the same day as they are dated.

Once the appeal or grievance is received, the timeframe in which a resolution must be made can be set by the state. However, the state cannot set that timeframe at more than 30 calendar days for an appeal and 90 calendar days for a grievance. If the MCO, PIHP, or PAHP upholds the adverse benefit determination, enrollees then have 120 days in which to request a state fair hearing.

Also, the new rule adopts the deemed exhaustion requirement from the private market rules (45 C.F.R. 147.136(b)(2)(ii)(F)) to ensure enrollees maintain access to a state fair hearing if the managed care plan does not adhere to the notice and timing requirements of resolutions.

As in most adjudicatory procedures, the appeals process allows for an expedited review. § 438.10(a) requires a managed care plan to maintain an expedited appeals process for urgent circumstances. Importantly, upon suggestion of commenters, § 438.410(a) was amended so that the described urgent circumstances include both physical and mental health aspects. Now, expedited resolution is necessary where taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function. The amendments further limit the timeframe that a state can set for the resolution of an expedited appeal. Now, a state cannot set the resolution timeframe for longer than 72 hours.

These changes impacting 42 C.F.R. Part 438, titled *Managed Care* will affect managed care contracts starting on or after July 1, 2017. Those contracts and the systems implemented by the Medicaid managed care plan must be compliant with the new appeals and grievance regulations found in subpart F of 438. However, the revisions to 42 C.F.R. Part 431, titled *State Organization and General Administration*, are effective immediately.

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