

Things to Consider When Your DMEPOS Vendor Goes Out of Business

Be aware of the legal issues that may surface.

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Author's Note: While a fluid situation at the time of publication, during the first few days after PAL's closure, there was uncertainty as to the status of new orders. This has largely been resolved, with the lab having returned to its customers any unprocessed casts and images, allowing your practice's discretion at choosing a new laboratory. Other raised issues (e.g., repairs) remain fluid and relevant. HIPAA, Antikickback and other issues discussed in this article remain largely relevant not only to this specific circumstance but for

other future business transaction(s) with DMEPOS vendors.

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the author's desire to provide further information, are noted in italicized print and were not reviewed by PICA's legal department.

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and was released to its policyholders in mid-October 2017. Other changes from the original email blast, due to either the fluidity of the situation or

Recently, PAL Orthotics Lab abruptly stopped taking new orders. What has become of its current orders, and whether it has transferred these orders to other existing labs, is not exactly clear. (see forward above and addendum at end).

A vendor going out of business poses several issues which should be of concern to your practice. First, these include HIPAA issues and how the Protected Health Information (PHI) you have provided the lab over the years is handled going forward. The second issue relates to the National Supplier Clearinghouse (NSC) and its requirements. The third issue has to do with potential anti-kickback violations. Finally, the last major issue requiring your attention is how to deal with devices you may have returned for repair.

HIPAA

From the HIPAA perspective, it is important to recognize that any com-

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pany that goes out of business is still responsible for safeguarding any Protected Health Information (PHI) you may have previously sent it (typically the patient's name, DOB, etc.). Often, the liquidating company will choose

or cancel them is an obligation that you as the supplier need to resolve in a timely fashion (30 days). If for any reason you cannot contact the lab that has ceased operations, you should send it a letter by traceable courier cancelling the order(s). You then will have the freedom to send

an inducement for referrals of other services (orthotic orders) from another entity.

Promotions of this type are questionable, and you should be wary of whether or not the specific offer made is legal. You should note that these anti-kickback statutes universally apply to patients with Medicare and Medicaid, irrespective of policy coverage. Despite foot orthotics not being covered under Medicare, the anti-kickback statute still applies. Thus, the use of a free scanner could be seen as an inducement for which you would be held accountable. A healthcare attorney who is well-versed in anti-kickback and inducement regulations should be consulted before accepting anything for free.

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to transfer this PHI as part of an asset transfer (its client list—your name and your scans with PHI) to another company. However, this must be done in a HIPAA-compliant manner between the two companies.

If the defunct lab transfers a current order to another lab, you should insist on obtaining a new Business Associate Agreement (BAA) from the lab to which the order was transferred. If you are notified that this asset transfer took place on previous orders, you should insist on obtaining a BAA from the lab to which the assets were transferred. *Certainly any new laboratories you choose to work with (where the laboratory is not involved in billing the patient or third party payer) that involve any PHI warrant a BAA. Practices are urged to check with their HIPAA compliance experts to verify that their BAA's are compliant and up-to-date.*

Supplier Standard Compliance

The NSC has standards and compliance issues requiring that suppliers have credit agreements with the vendors with whom they do business. This is particularly true for those items not normally stocked by the supplier, such as custom fabricated items (Supplier Standard #4). Thus, you should obtain a credit application from the new lab and execute it, along with a BAA (see above), as soon as possible.

The NSC also has a requirement that you provide your patients with orders in a timely fashion. Not knowing if the defunct lab will fill your orders, transfer them to a new lab,

the same scan(s) (or casts) with new orders to the lab of your choice. The same would be true if the lab tells you it is not filling any orders at all and it has not transferred the order to another lab. If, for whatever reason, you cannot fulfill the order within 30 days, you should contact your patient and provide him/her with the reasons for any delay in providing the DMEPOS.

Anti-Kickback Statute and Inducements for Referrals

Many recent advertisements

Devices Currently Under Repair

At first, this may seem to be the most frustrating of all issues you may need to deal with when a lab goes out of business. This would especially be true if the defunct lab has not transferred its assets to a new lab. The devices sent for repair are possibly being held in a locked building beyond your ability to obtain them. If the as-

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of other orthotics labs have been courting customers of the defunct lab with promotions, including the offer of transferring your data (scans) from the defunct lab's scanner to their software in order to fulfill your orders. Simultaneously, there is an offer for free scanners to new customers who are transferring their business from the defunct lab. The former was addressed in the HIPAA section of this article. The latter raises questions regarding potential anti-kickback violations as they apply to the provision of free goods and services (scanners, first free device, etc.) from one entity as

sets were transferred to a new lab, the new lab may not be under any obligation to honor the warranties of the defunct lab (subject to state and/or federal regulations). In either case, there are some remedies available to you depending on the specific circumstances.

• Assets Transferred and New Lab Honors Warranty

This is the simplest scenario where the new lab repairs the device and returns it to you. There would be no charge to the patient and likely no charge to the third-party payer.

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• **Assets Transferred and New Lab Does Not Honor Warranty**

If it is less than 90 days since dispensing, Medicare will not pay for the repairs as these are global to the fee it paid for casting, fabrication, fitting, and dispensing. It will be your responsibility to pay for those repairs.

• **Assets Not Transferred and One Cannot Obtain Device from the Lab**

Under these circumstances, you may be able to recover most if not all of your losses by following the guidelines found in Chapter 5 Section 9 of the Supplier Manual (<https://www.cgsmedicare.com/jc/pubs/pdf/>

Finally, you have a legal and moral obligation to satisfy the patient either by repairing or replacing the existing device.

chpt5.pdf). This section describes an item which is lost (due to a one-time event) or stolen. Submit a claim for the replacement device with the additional RA modifier (in addition to the KX and RT/LT modifier) in order to indicate the one-time event resulting in the device's loss. You should also include a note in the electronic narrative field (or via a letterhead attachment if submitting by paper). This should indicate some proof of the demise of the lab. If the claim is rejected, you should be able to successfully appeal via the usual re-determination method. For non-Medicare beneficiaries, the regulations regarding rebilling for lost property may vary and you should check with your individual carriers.

In summary, when one of your vendors goes out of business, you have several issues to deal with. The primary issue is HIPAA compliance and understanding that the liquidating company is still responsible for securing the PHI under the terms of the BAA. Should the defunct company transfer the PHI as part of an asset transfer to another company, you should obtain a BAA with that new company, especially if you intend to do business with it in the future.

The second issue of concern is the regulations promulgated by the NSC. A new credit application with the new company must be completed in order for the new company to provide you with a signed and dated credit agreement (Supplier Standard #4). Be sure the terms are consistent with those listed on the NSC website under the Standards and Compliance tab (<https://www.palmettogba.com/palmetto/providers.nsf/DocsCatHome/National%20Supplier%20Clearinghouse>).

You should consult with an attorney well-versed in

anti-kickback statutes, should you consider accepting an offer for any free equipment.

Finally, you have a legal and moral obligation to satisfy the patient either by repairing or replacing the existing device. Any legal recourse you may choose to take against the defunct company may take years to resolve with those costs easily exceeding the cost of replacement. Depending on your individual circumstance, it may also be possible to rebill the third-party payer.

Some Additional Comments: *At press time PAL appears to have been (or was in the process of) returning casts, scans, etc. to its customers—in effect, providing your practice the ability to select a new laboratory. No official word from officials at PAL regarding the fate of devices sent for repair. PM*



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