AOPA In Advance SmartBrief
Breaking News
August 9, 2016

AOPA Headlines:

AOPA Submits Comments to the FDA on 3-D Printing

AOPA has submitted comments on the publication entitled *Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff* which was published in the Federal Register on May 10, 2016. (Read that publication.)

AOPA submitted comments pertaining only to additive manufacturing in the design and fabrication of external prosthetic components and orthotic devices, specifically through the use of 3-D printing. The comments submitted reflect that AOPA does not believe that either additional or lesser regulatory burdens should be placed on manufacturers of prosthetic components and orthotic devices solely based on the decision to utilize an additive manufacturing process into their fabrication protocols.

An excerpt of the comments:
"AOPA firmly believes that the manufacture of a prosthetic component or orthotic device is only a small part of the creation of an artificial limb or orthoses that meets the individual needs of a particular patient. The components that are included in the completed prosthesis or orthosis must be adjusted, and aligned by a properly educated, trained, and certified or licensed healthcare professional such as an orthotist or prosthetist.

AOPA fully supports the role of the FDA in ensuring that medical devices, including prosthetic and orthotic devices remain safe and effective, but believes the current direction of the FDA, as outlined in the draft guidance document, to not alter regulatory requirements solely as a result of the use of additive manufacturing is appropriate…. (FDA's stated position) "will encourage the development of technology while assuring that devices created through additive manufacturing remain safe and effective for use by the general public, and maintaining consistency and a level regulatory playing field for the devices without regard to the specific method of fabrication employed by the manufacturer."

Read the comments submitted.

CMS Reminds DMEPOS Providers to Report Changes Within 30 Days

The Centers for Medicare and Medicaid Services (CMS) recently published a Medlearn Matters article reminding Medicare providers and suppliers of their responsibility to report any changes to their provider file in order to maintain Medicare billing privileges.

For DMEPOS suppliers, which include O&P providers, any changes to the information reported on the CMS 855S enrollment form must be reported within 30 days of the change. Reporting these changes is achieved by completing the relevant sections of the CMS 855S enrollment form and returning it to the National Supplier Clearinghouse.

A copy of the Medlearn Matters article may be viewed by clicking here.

Questions regarding this issue may be directed to Devon Bernard at dbernard@aopanet.org or Joe McTernan at jmcternan@aopanet.org.

Don't Miss the Fun: Pre-Register for the 9th Annual Wine Tasting & Auction

If you haven't already done so, it is not too late to pre-register for the 9th Annual Wine Tasting & Auction being held on September 9 at 6:00 pm during the 2016 AOPA National Assembly in Boston, MA. For more information click here.

Don't let the name fool you, the auction includes more than just wine. We have bourbon, scotch, beer, cigars and special surprise items, plus a stocked open bar. But don't worry we also have several lots of world class wines. Take a peek at last year's catalog for an idea of the type of items you may bid on. View the previous catalog here.

This year's event will also feature a few special Boston inspired items, including private tour packages of local New England vineyards/distilleries and signed Red Sox and Patriots memorabilia.

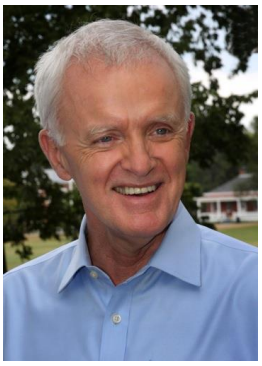
You may pre-register for the 9th Annual Wine Tasting & Auction here or you may pre-register when you register for the 2016 AOPA National Assembly. This event is the perfect way to enjoy an evening with your friends and colleagues.

Assembly Keynote Speakers Announced

Announcing our 2016 Assembly Keynote Speakers

The 2016 National Assembly will feature two powerful keynote speakers

Friday, Sept 9

	**David Gergen** is a senior political analyst for CNN and has served as an adviser to four U.S. presidents of both parties. He is a professor of public service at the Harvard Kennedy School and the director of its Center for Public Leadership. In 2000, he published the best-selling book, *Eyewitness to Power: The Essence of Leadership, Nixon to Clinton.* Read more.
	**Senator Bob Kerrey** served in the Senate for 22 years, and one term as Governor of Nebraska. He fought in Vietnam as a Navy SEAL and was awarded the Medal of Honor for heroism in combat during a battle in which he became a below-knee amputee. He has been a champion for O&P, weighing in on the 2015 draft Lower Limb LCD and participating in AOPA's 2016 Policy Forum. Read more.

99th AOPA National Assembly ~ Sept 8-11 ~ Boston

Register today for the country's oldest and largest meeting for orthotic, prosthetic and pedorthic professionals. Take advantage of five dedicated education tracks, providing the most relevant education for orthotists, prosthetists, technicians, pedorthists and business managers.

Download **AOPA 365** to peruse sessions, save your schedule, connect with alumni and more, PLUS stay connected with AOPA all year round.

Register Now

Congress Being Urged by Some in "Big Medicine" and CMS, to Downgrade or Eliminate Stark Laws/Rules That Preclude Self-Referral

Earlier this year, Medicare implemented a new policy on Comprehensive Care of Joint Replacement. While positioned as a pilot test, *all* hospitals were forced to be involved. Under this new program, hospitals are given financial incentives to reduce the total cost for hip and knee replacements. If hospitals succeed in driving down the total costs, the hospitals keep a portion of the savings. If the hospitals fail to drive down the total costs, the hospitals will have to pay a portion of the tab. If you are a Medicare patient, do you think this means you will receive the best quality of care or the cheapest? If you said "cheapest", keep reading to find out how Stark Rules could protect you from these "risk-sharing" deals.

The Stark Rules, also known as the Stark Laws, were created to help control conflicts of interest in medical care. For example, they limit certain aspects of physician ownership of facilities to which physicians refer patients, including those facilities that provide blood tests and X-rays. In addition, they restrict other actions which could compromise the fundamental principle that patients can always look to their health care providers, first and foremost, to advocate for what is best for them as patients – not what makes them the most money.

As CMS/Medicare and other payers try to move aggressively toward "valued-based purchasing" and provider risk-sharing, CMS, private payers, and hospitals—all of whom stand to profit if others, namely providers, can be enticed to shoulder some of the risk and uncertainty that goes along with risk sharing—have found the Stark rules inconvenient and have beseeched their friends in Congress to do away with or, at least, substantially reduce the 'teeth' in the Stark Rules' prohibitions on provider conflict of interest. It is a game of big medicine vs. the little guys—patients and providers. What we talk about as risk sharing today is very similar to what we used to call capitation, managed care, or HMOs. If you think those things made things better for patients, then sure, do away with the Stark Rules and allow the system to create deals that operate to incentivize reductions in care to patients.

There is one aspect of how CMS has interpreted the Stark Rules that has proven particularly controversial, that being the in-office ancillary services (IOAS) exception, which among a number of other instances where it has permitted a measure of physician self-referral that the Stark Rules would NOT permit, this IOAS exemption granted by CMS has been used by some physicians to themselves deliver and bill to patients for prosthetics and/or orthotic devices supplies within the physician's office or a related physically adjacent facility. While AOPA and others oppose these broad interpretations of the in-office ancillary services exemption, it is important to recognize that eliminating the Stark Rules would open the door to even wider, essentially unlimited self-referral by hospitals, rehab facilities, as well as physician offices. If you oppose the exemption CMS has granted in the in office ancillary services exemption, you very likely favor the underlying broad prohibition on self-referral (by physicians and other providers) that is embodied in the Stark Rules. The bottom line, after all, is assuring the highest possible level and quality of patient care for prosthetic and orthotics patients.

However, if the Stark Rules are eliminated, Payers could set mechanisms to award all the business to the lowest bidder…again, patient beware. Keep your eyes open, and let your voices be heard—with Congress, with your state legislators and others—it's important!

DME MACs Release New Coding Guidelines for O&P Suppliers

The four DME MACs recently released a joint correct coding bulletin reminding DMEPOS suppliers that it is each supplier's responsibility to select the proper HCPCS codes for billing. The full bulletin may be found here.

To aid suppliers in their selection of the proper HCPCS code(s) the DME MACs provided the following tips:

- Check the PDAC Product Classification Lists
- Review DME MAC publications for coding bulletins and coding guidelines
- Refer to the long code descriptor and select the code with the descriptor that most closely describes the item you are providing.
- Most code narratives are written broadly to be all-inclusive. You may not find a specific code that perfectly matches a product. Use the code that most closely describes the item rather than a NOC (not otherwise classified) or miscellaneous code.
- Review LCDs & Policy Articles for coding guidelines for additional information on the characteristics of products that meet a specific HCPCS code.
- Don't select a code based upon the fee schedule amount. HCPCS codes describe the product not the price.
- Check with the PDAC. The PDAC may provide information, outside of a formal product review, that will assist you in code selection.

The bulletin also stressed that the DME MACs and the PDAC are the only entities that have the authority to assign HCPCS codes to specific products and if a supplier chooses to follow coding recommendations from outside sources; that these recommendations will have no "official standing" during a possible claim review/audit.

AOPA is currently analyzing the joint bulletin and is working with the DME MACs to obtain some clarification and guidance on specific points raised in the bulletin. We will keep you posted of any new information.

Questions? Contact Devon Bernard at dbernard@AOPAnet.org or Joe McTernan at jmcternan@AOPAnet.org

Survey on Research Priorities in O&P

BCIT is conducting a survey, which should take 10-15 minutes to complete, on research topics to benefit practitioners and those who use prosthetic and orthotic devices. Everyone who participates can have the results delivered to their inbox once the survey is completed.

Project Title: Prosthetics and Orthotics: Feedback on Research Priorities

Principal Investigator: Silvia Raschke, PhD (BC Institute of Technology, Canada)

Purpose: To establish a research strategy and platform which identifies needs and priorities in the field of Prosthetics and Orthotics.

To examine people's perceptions regarding what research topics would be of most benefit to clinical practitioners and those who use prosthetic and orthotic devices. We are interested in

your perspective, and you are invited to participate in this research study by completing an online questionnaire (link provided below).

You can take part if you are fluent in English and have experience or exposure to prosthetics and orthotics.

Take the survey.

RAC Audits Placed on Hiatus Again

The Centers for Medicare and Medicaid Services have notified the four existing RAC contractors that as a result of the upcoming award of new RAC contracts, current RAC audit activity will be placed on hiatus to allow the RACs to complete their open audits prior to the completion of their contracts. CMS has provided the following dates to the RAC contractors regarding current audits.

- May 16, 2016 - the last day that a Recovery Auditor could send Additional Documentation Request (ADR) letters or semi-automated notification letters.
- July 29, 2016 - the last day that a Recovery Auditor may send notification of an improper payment to providers. This includes sending a review results letter or no findings letter, and/or providing a portal notification to each provider.
- August 28, 2016 - Recovery Auditors will complete all discussion periods that are in process by this date. Recovery Auditors continue to be required to hold claims for 30 days, starting with the date of the improper payment notification (via letter or portal) to the provider, to allow for discussion period requests.
- October 1, 2016 - the last day a Recovery Auditor may send claim adjustment files to the MACs.

While this is good news for O&P providers in the short term, it is not a signal that the RACs are going away any time soon. It is simply a pause to allow for a smooth transition to new RAC contractors, including the single, national RAC contractor that will focus on claims for DMEPOS, Home Health, and Hospice services. While this announcement may result in a temporary slowdown of RAC activity, it is important to remember that claims that are submitted today may be selected for audit by RAC contractors in the future.

Questions regarding this issue may be directed to Joe McTernan at jmcternan@aopanet.org or Devon Bernard at dbernard@aopanet.org.

August 10 Webinar: Supplier Standards – Are You Compliant?

August 2016

10

1:00 PM Eastern

Join AOPA for a one hour webinar and earn 1.5 CEs, while learning everything you need to know about appeals. During this webinar, participants will:

- Do you have a proper contract with your vendors on file?
- Are you required to have a surety bond?
- Can you use contracted employees?
- What happens if you're non-compliant with the Medicare Supplier Standards? Register here.

Join the Coding & Billing Experts in Las Vegas!

The AOPA Coding & Billing Experts are Coming to Las Vegas!

AOPA's next Coding & Billing Seminar will be in Las Vegas! Don't miss this opportunity to get the most up-to-date information to advance your O&P practitioners' and billing staff's coding knowledge.

Join your Colleagues November 14-15 in Las Vegas!

At this seminar you will:

- **Receive up-to-date information on Prior Authorization and other Hot Topics**
- **Ensure your Proof of Delivery meets Medicare Requirements**
- **Learn how to assess risk areas in your practice**
- **Learn successful appeal strategies and hints to avoid claim denials**
- **Practice coding complex devices, including repairs and adjustment**
- **Attend break-out sessions for practitioners and office staff**
- **Earn 14 CEs**

Where else can you get two jam-packed days of reliable, valuable O&P coding and billing information? Learn more.

Register Now

Upcoming AOPA Events

August 10, 2016 — *Supplier Standards: Are You Compliant?*
AOPA Webinar
Learn more and register here

September 8-11, 2016 — *AOPA National Assembly*
Boston, MA
Learn more and register here

September 14, 2016 — *Fill in the Blanks: Know Your Forms*
AOPA Webinar
Learn more and register here