American Orthotic &
Prosthetic Association

August 25, 2015

Shantanu Agrawal, MD
Deputy Administrator and Director
Center for Program Integrity
Centers for Medicare and Medicaid
7500 Security Boulevard
Baltimore, MD 21244

Laurence Wilson, Director
Chronic Care Policy Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Agrawal and Mr. Wilson:

The text of this letter below this paragraph is identical to the letter I had forwarded to Laurence Wilson on August 13, 2015. Mr. Wilson had indicated that he thinks the letter would be more appropriately directed to the Director of Program Integrity. Inasmuch as the contractor action which we are contesting is almost identical to an action taken by another contractor, PDAC, which (at least has been under Mr. Wilson's jurisdiction) in late 2011 prompted our appeal to Mr. Wilson for a correction in light of the content of device labeling (including model number and serial number having been assigned to FDA, and not to CMS). Due to the fact that in response to our letter and legal memos then, the PDAC did indeed withdraw its proposed action, I have decided that I should send the letter addressed to both of you jointly. If there is any overlap in responsibility as to this topic, I trust that you will resolve it, and if this is to be resolved under, and an answer to come from, the Office of Program Integrity, I am sure Dr. Agrawal may need, at minimum to consult with Mr. Wilson as to the history of the matter, dating back to PDAC in late 2011.

On February 12, 2015, CMS' DME MAC contractors informed O&P patient care facilities of its intent to impose new Proof of Delivery requirements that would provide that the only 'safe harbor' to demonstrate acceptable delivery would be if someone, presumably the manufacturer, although the patient care professional could undertake in an ad hoc manner to incorporate certain information onto the device itself or on its accompanying labeling. As the only alternatives are very uncertain, and as the DME MACs have stated they will no longer accept the HCPCS code descriptor—which was after all created to describe the device with great clarity and certainty—as an acceptable description in the absence of a serial number, the new policy amounts to a de facto imposition by CMS/DME MAC contractors of the requirement for placement of a serial number on all devices as a CMS requirement. This is not the first time this issue has been raised in discussion with this agency. In late, 2011, the PDAC informed manufacturers of a then-new requirement to include a model/serial number and identifying text in the labeling of all O&P devices.

We approached CMS/your office then indicating that we were unaware of CMS/PDAC possessing specific authority to require product labeling on medical

devices, although we have been aware that specific legislative authority as to medical device labeling was afforded to the Food and Drug Administration, as well as being aware that FDA has statutory authority to create a regulatory structure for Unique Device Identifiers (UDIs).

At that time we said: "This issue demands a balance of expertise in the areas of CMS/Medicare laws, as well as FDA law relating to foods, drugs, cosmetics and medical devices. Appended to this report, and referenced herein, is a summary analysis presented by the law firm of Foley Hoag, reflecting the knowledge and experience, among others, of Thomas Barker, Esquire, formerly General Counsel to the U.S. Department of Health and Human Services, relating to CMS/Medicare issues. Also attached is a similar analysis on FDA law, which reflects the knowledge and experience of Richard Cooper, Esquire, formerly the Chief Counsel to the U.S. Food and Drug Administration. The respective analyses from the firms of Foley-Hoag and Williams and Connolly are attached, and these reports essentially speak for themselves, and they should be viewed in tandem."

Based on these two analyses we stated that CMS needed to withdraw the requirement articulated by its PDAC contractor communication on September 22, 2011 of any statements mandated to be affixed to specific medical devices, in advance of the originally stated effective date of February 1, 2012. In response, we received a notification from the PDAC that this requirement was being withdrawn.

So, there is a sense of déjà vu as a different CMS contractor again tries to impose essentially the same labeling requirement. This communication is comprised of three parts.

1. What is wrong with the new Proof of Delivery requirement, and in some respects that includes some of the things that have not changed since early 2012 when CMS recognized the problem and withdrew the PDAC requirement;
2. A recitation of key aspects of FDA and HHS/CMS governing law still applicable to this de facto imposition of an CMS-mandated labeling, model/serial number process;
3. A brief analysis of relevant case law/legal decisions and analysis which demonstrate collectively that just as was the case in the 2011-12 efforts, so this new parallel requirement must also be withdrawn.

We reiterate the request that again, this 2/12/15 policy needs to be reversed/withdrawn with denials based on it reversed. Thank you, and please do not hesitate to contact me if there are any questions regarding either or both of the attached analyses.

Sincerely,

Thomas F. Fise
Executive Director

cc: Andy Slavitt, CMS Administrator
AOPA Board of Directors

IV. RECENT PROOF OF DELIVERY REQUIREMENTS: BOTH SUBSTANTIVE AND AUDIT CONCERNS

The below is a good background, which might fall under the general heading – "If it Ain't Broke, Why Do the DME MACS Insist on Trying to Fix It?"

(1) The first and most compelling point is the fact that the **DME MACs will no longer accept the HCPCS code descriptor as a narrative description of the device when a brand name or model number/serial number is not available**. The example I would offer is on spinal orthoses where the code descriptor is so detailed that it describes the anatomical landmarks that the orthosis extends to as well as the level of control it provides. I cannot think of a more complete narrative description that can be included on a proof of delivery. Take L0486 as an example. The code descriptor is as follows: TLSO, triplanar control, two piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from symphysis pubis to sterna notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the saggital, coronal, and transverse planes, includes a carved plaster or cad-cam model, custom fabricated. **According to the DME MACs, the code descriptor, which describes the specific height of both the anterior and posterior sections of the orthosis as well as the specific level of control it provides, is not acceptable for them to determine that the device provided was coded properly.** That is simply a *ridiculous* statement.

(2) The second point relates to the DME MACs potentially again overreaching HHS/CMS' legal authority to dictate product labeling and branding, relating specifically to the"preferred" method of documenting the specific information about the device that was provided. The DME MAC bulletin, a link to which is below, indicates that "the preferred method is use of a brand name and model number, brand name and serial number or manufacturer name and part number to identify the product." The bulletin then goes on to state, "If this type of information is not available for the product, suppliers may use a detailed narrative description of the item; however, it must contain sufficient descriptive information to allow a proper coding determination. This "narrative description" of the item is not the HCPCS code narrative." The concern is that **while the bulletin states that a brand name, model number/serial number is not required, that in instances where a manufacturer may choose not to assign a brand name or model number/serial number to a prefabricated product, the DME MACs may deem the proof of delivery documentation as invalid leading to unnecessary claim denials**. There is currently no requirement that Class I products must have any form of unique identifier as was addressed in the recent UDI rule, and *products assigned by FDA to Class 1, exempt from GMPS (as is the case for most O&P devices) are not obliged to carry any brand name, model number or serial number.* **It is unfair for a device which fully complies with all requirement imposed by the government body that has been authorized by Congress to control medical device labeling may be disadvantaged as to reimbursement via a 'preference' of contractors for an agency that does not have any authority from Congress to dictate or require labeling.** The fact that, for whatever reason, a manufacturer chooses not to brand a particular device should not impede the ability for O&P facilities to be reimbursed by Medicare when providing it. Essentially this **same issue has been argued and decided previously (see the attached).**

CONCLUSION, Letter of Richard Cooper, Esquire

Williams & Connolly, Former FDA General Counsel, 12/22/11

FDA, not PDAC or CMS, has been granted explicit and unique statutory authority under the FDCA to create and administer a UDI system and to regulate medical device labels and labeling generally. PDAC and CMS may legitimately ask device manufacturers to "tag" for purposes of identification single units of devices they submit to PDAC for coding review, but PDAC and CMS may not impose requirements on the labels or labeling of devices being released for sale in the market. That is the province of FDA. Therefore, the authorities and analysis presented in the foregoing discussion require that CMS withdraw the PDAC requirement, and that PDAC defer to FDA with respect to requiring identifiers on devices.

Excerpts from Attorney Cooper's Rationale

A SEPARATE DEVICE-IDENTIFICATION REQUIREMENT IMPOSED BY PDAC WOULD FRUSTRATE CONGRESS'S PURPOSE OF HAVING A SINGLE UDI SYSTEM, AND WOULD CREATE UNNECESSARY BURDENS ON MANUFACTURERS, HEALTHCARE PROVIDERS, AND DATABASE USERS.

A A Separate Device-Identification Requirement Would Frustrate Congress's l)purpose of Having a Single UDI System.

By specifying that FDA should create a unique device-identification system, Congress plainly intended that each device have only one identifier, and that that identifier conform to a system that would be created and administered by FDA. That congressional intent precludes CMS or any other agency from creating a second device~identification requirement, which would cause the identifiers in FDA's system to be not unique. Therefore, whether PDAC intends its device-identification requirement to serve as a UDI system or to serve only a more limited purpose of facilitating billing and reimbursement activities, PDAC's creation of a second device identification requirement would frustrate the congressional purpose that is manifest in FDCA section 519(f).

B. A Separate Device~Identification Requirement Imposed by PDAC Would Create Unnecessary Burdens on Manufacturers, Healthcare Providers, and Database Users.

Implementation of a device-identifier system necessarily involves substantial investments of time, money, and energy. Equipment and software must be developed and purchased for reading the identifiers, databases must be reprogrammed to track the new data, and linkages must be established between the new identifiers and any prior identifiers previously in use for each

device. *See* Eastem Research Group, Unique Identifiers for Medical Devices .....Final Report 4-2 to 4-3 (Mar. 22,2006) (report prepared for FDA), *available at* http://www.fda.gov! MedicalDevicesIDeviceRegulationandGuidancelUniqueDeviceIdentification/ucm054169.htrn. As the research regarding UDI systems has established, the setup costs are likely to be substantial. *See iei*

Inc PDAC requirement would compel manufacturers, providers, and database users to pay these costs twice: once to implement the PDAC requirement, and again to implement FDA's system. Moreover, government data-collection systems and databases would also have to be revised at least twice (and, possibly, more than t\vice if FDA's 001 system or PDAC's device identification requirement changes or if other agencies impose additional device-identification requirements). Although it is possible that some of the equipment used to implement the PDAC requirement could be used for FDA's system, such savings are likely to be cumbersome to realize. To achieve the savings, the two systems would have to use compatible technology. Consequently, database users that purchase equipment and software to work with the identifiers required by PDAC would have to guess at what FDA's system will be, so that they can purchase equipment compatible with both. Moreover, sunk costs incurred to deal with PDAC's identifiers would constrain FDA's choices and encumber its design process. Providers -and government agencies -would want FDA to choose a system compatible with the equipment and they had purchased to implement PDAC's identifiers. FDA would face pressures to design its system accordingly, even at the potential loss of effectiveness; and its implementation of the UDI system, which was statutorily mandated with the specific understanding that FDA would create and administer it, would be encumbered by the process of investigating this issue of backward compatibility.

Moreover, putting PDAC identifiers into circulation would increase the likelihood of errors by medical personnel. even if PDAC's identifiers ultimately gave way to a system designed by FDA. Faced with an older set of identifiers under the PDAC requirement and a newer set under FDA's system, medical providers and database users (including governmental database users) would have to transition from one set of identifiers to another. 'During this shift, errors would be likely to occur, as people and database systems adjusted. The risk of errors would be still higher if product identifiers required by PDAC were to continue to be used even after FDA's system had become operational. In that scenario, devices would need to have two identifiers at the same time; and medical staff and database operators would have to choose which of the two to use or to use both. Indeed, however tempting it might be to think that PDAC's identifiers would vanish exactly when FDA's became operational, realism counsels that there would almost certainly be a period of overlap. During that period, avoidable errors in medical care and in data analysis almost certainly would occur.

It would be unreasonable to impose these burdens and costs in order to have device identifiers before FDA promulgates its UDI system.

A SEPARATE DEVICE-IDENTIFICATION REQUIREMENT IMPOSED BY PDAC WOULD BE CONTRARY TO FDA'S PLENARY AUTHORITY TO REGULATE DEVICE LABELS AN!> LABELING.

As explained *supra* at page 2. Congress has delegated to FDA, through the Secretary, plenary authority to regulate device labels and labeling; and FDA has exercised that authority.

I understand that Thomas Barker of Foley Hoag LLP, has opined that the statutes CMS administers do not authorize it to impose requirements for device labels or labeling. If, nevertheless, CMA can impose such requirements under general statutory authority, then other federal agencies that also lack specific authorization to impose requirements on device labels and labeling could impose such requirements under their general statutory authority. For example, The Department of Homeland Security could require that the labels and labeling of imported devices (and those of other imported products regulated by FDA) bear information relating to product identification (to accord with that Department's data-management systems), importation and place of manufacture. The Department of Defense ("DoD") could require that the labels and labeling of

devices (and those of other products regulated by FDA) that it purchases bear information relating to product identification (to accord with DoD's data-management systems) and appropriate military uses. The Department of Veterans Affairs could require analogous information on devices and drugs it purchases for its programs for veterans. The Department of Agriculture could impose an analogous requirement as to food purchased for the school lunch program. And so on.

Plainly, such proliferation by multiple agencies of requirements for product labeling would unduly interfere with the systems for labels and labeling created and administered by FDA during the decades since the enactment of the FDCA in 1938. Multiple such requirements would also unduly burden manufacturers.

Moreover, depending on whether, and if so how, such agencies would regulate the size and location of the information they would require, their requirements could make it more difficult for physicians, consumers, and others to use product labels and labeling effectively and efficiently. Such an effect would obstruct the major purpose of FDA's regulation of product labels and labeling.

CONCLUSION, Letter of Thomas Barker, Esquire

Foley Hoag, Former HHS General Counsel, 12/20/11

We believe CMS should instruct the PDAC to withdraw the proposed product labeling requirement. First, the Secretary of HHS has never granted labeling authority to either the Contractor or to CMS. Instead, this authority has been explicitly delegated to the FDA. As such, CMS and its contractor should refrain from prescribing UDI or medical device labeling requirements, and defer to the FDA's explicit authority in these areas.

Excerpts from Attorney Barker's Rationale

With regard to the PDAC's explicit authority to regulate the content of a medical device label, we are aware of no authority granted to either the contractor or to CMS by the Secretary of HHS to regulate labeling. The FFDCA is the primary law under which the FDA takes actions against regulated products, including medical devices. Specifically, sections 201(k) through 201(m) of the FFDCA address labeling definitions, sections within Chapter III address prohibited acts including "adulteration" and "misbranding" of medical devices,

1 The PDAC announcement can be found online at ht!Ps:llwww.dmepdac.com.

2 *See* FFDCA § 20 I (k), 21 U.S.C. 321. *See also* 21 CFR Part 801.

and sections within Chapter V set forth specific instances whereby medical devices will be considered to be adulterated or misbranded. Although the statute generally authorizes the Secretary of HHS to enforce the provisions of the FFDCA, the Secretary has delegated its authority to the Commissioner of Food and Drugs (with authority to redelegate) "functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act.,,3 We believe that CMS contractors thus lack any explicit authority to place labeling requirements upon manufacturers -this is the sole jurisdiction of the FDA.

It is perhaps less clear whether or not PDAC or CMS have implicit authority to place labeling requirements on products submitted for coding verification purposes. There is an argument that because the PDAC is not regulating device labels, but rather imposing a requirement on specific categories of products that it is billed for and pays for; such a requirement falls well within the scope of CMS' general authority to determine medical necessity or ensure devices meet the durability, utility, and appropriateness requirements for coverage.[4] However, nowhere in the statute authorizing CMS' coverage authority is the Agency granted authority to amend, append, or modify a device label, which remains the exclusive jurisdiction of the FDA. Medicare coverage authority extends to determinations of whether an item or service is "reasonable and necessary for the diagnosis or treatment of illness or injury." Beyond this initial determination, Congress also provided a general framework within which categories of benefits could be covered by the Agency and its contractors-naming certain categories as covered and naming other products and services categories as excluded.[6] Yet, neither the medical necessity determination, nor the category determination, grants CMS or its contractors the authority to regulate the content of a device label.

Having extensively reviewed the statutes and regulations governing CMS authority we have found no evidence that CMS has ever been granted authority to require certain information on a device label. It is notable that, as the FDA continues the process of developing a framework wherein the label of a device will be required to bear a unique identifier, CMS's role is relegated to that of a stakeholder.[7] At a September Unique Device Identification workshop, Tamara Syrek Jensen, Deputy Director of the Coverage & Analysis Group at CMS described CMS' role as that of an "end user" and not as regulator with regard to a product's label. While the PDAC and CMS will be given significant deference should this issue rise beyond a discussion with the contractor, we maintain there is a strong

3 FDA Staff Manual Guides, Volume II -Delegations of Authority, Regulatory Delegations of Authority to the Commissioner Food and Drugs, SMG 1410.10 (Effective 5/18/2005).

4 *See* Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, Section 110.

5 §1862(a)(1)(A) of the Act, 42 U.S.C. § 1395y(a)(1)(A).

6 In addition to the medical and other services listed in § 1861(s) of the Act, 42 U.S.C. § 1395x(s), examples of items and services that are explicitly covered or not covered are found in § 1861(n) of the Act (durable medical equipment), 42 U.S.C. § 1395x(n). *See also id.* at § 1862(a)(7) and (8) of the Act (specifying some exclusions from coverage), 42 U.S.C. § 1395y(a)(7), (8).

7 *See generally* the Food and Drug Administration Amendments Act of2007, Pub. L. 110-85, requiring the establishment of a Unique Device Identification System.

argument that PDAC lacks the authority to require certain information on a permanently affixed label. This view is confirmed and reinforced by the memorandum by Richard Cooper, Esquire, which accompanies this document.

For the foregoing reasons, we believe CMS should instruct the PDAC to withdraw the proposed product labeling requirement. First, the Secretary of HHS has never granted labeling authority to either the Contractor or to CMS. Instead, this authority has been explicitly delegated to the FDA. As such, CMS and its contractor should refrain from prescribing UDI or medical device labeling requirements, and defer to the FDA's explicit authority in these areas.

Sincerely,

Thomas Barker
Ross Margulies

WINSTON
&STRAWN
LLP

1700 K Street, N.W.
Washington, D.C. 20006-3817
T: +1 (202) 282-5000
F: +1 (202) 282-5100
www.winston.com

THOMAS L. MILLS
Washington D.C. Managing Partner
(202) 282-5714
Tmills@winston.com

Gentlemen and Ladies:

You've asked us to address whether the recent Bulletin issued by all of the DME MACs setting forth new "Proof of Delivery" ("POD") requirements for billing Medicare and Medicaid for Orthotics and Prosthetics was lawful. In our view, from an administrative law and health care regulatory standpoint, it is not. Following is a brief summary of the more extensive analysis we provided you.[1]

Even if CMS had the authority to require the additional labeling requirement – which, as shown, it does not – the requirement so imposed violates the Administrative Procedure Act ("APA"). Under the APA, an agency action is a legislative rule if "the agency intends to create new law, rights or duties". *General Motors Corp. v. Ruckelshaus,* 743F.2d 1561 (DC Cir. 1984). *See also General Electric Co. v. EPA*, 290 F. 3d 377, 382.83 (D.C. Cir. 2002) ("an agency pronouncement will be considered binding as a practical matter if it ... is applied by the agency in a way that indicates it is binding"), and *Texas v. United States*, 787 F. 3d 733, 382-83 (D.C. Cir. 2002) (explaining that there are "two criteria to determine whether a purported policy statement is actually a substantive rule: whether it (1) imposes any rights and obligations and (2) genuinely leaves the agency ... free to exercise discretion.

Here the Bulletin states unequivocally that using an HCPCS code narrative is "not adequate for the POD purposes". Accordingly, any POD documents that use the HCPCS code narrative as the detailed description of the item "will be denied for insufficient delivery information" and the associated reimbursement claim will be denied. And although stating that use of the three preferred methods of identification are not the only methods acceptable, as a practical matter, they are.

The conclusion that the new POD requirement is a legislative rule means that it must be subjected to notice and comment under the APA, 5 U.S.C. § 553 (b), (c) 2012. CMS has not satisfied that requirement, and the DME MACs have no legislative rulemaking authority. So the POD proposal fails for that reason alone.

[1] We will not repeat here the extensive and erudite treatment by Foley Hoag LLP and Williams & Connolly LLP of the lack of CMS' authority to require serial numbers or other labeling requirements entrusted by federal law to the FDA. We look rather at administrative and health care law aspects of CMS' proposal, and, as next shown, the proposal fails in those respects also.

Moreover, the APA requires agency action to be set aside if it is arbitrary and capricious. 5 U.S.C § 706 (2) (A) (2012). In the seminal case, *Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 42-43 (1983) the Supreme Court held that the "agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."

Here, there is a wholesale failure of the agency to identify the basis for the POD requirement: CMS has identified no over-arching problem of billing for orthotics and prosthetics relating to mis-identification of the item: CMS has found NO facts compelling the adoption of an across-the-board POD requirement for orthotics and prosthetics. And, even if it had, it articulated no rational or any basis whatsoever for concluding that the HCPCS description is no longer sufficient for proof of delivery purposes.

Taken together with the compelling arguments of Foley Hoag LLP and Williams & Connolly LLP, that the labeling requirement is *ultra vires* CMS' authority, the POD proposal is arbitrary and capricious, and therefore unlawful, for multiple reasons.

Tom Mills
Chair, Health Care Practice
Winston & Strawn LLP