July 28, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items

Dear Administrator Tavenner:

On behalf of the American College of Physicians, we are writing to share our comments on the proposed rule for the *Medicare Program Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items*. ACP is the largest physician medical specialty society, and the second largest physician membership organization, in the United States. ACP members include 141,000 internal medical physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP supports CMS' objective in this proposed rule of ensuring beneficiary access to care and protecting the Medicare Trust Funds without placing undue burden on clinicians and suppliers. We believe that changes to the Medicare benefit structure should not increase the administrative burden on physicians and other health care professionals. Our review of this proposed rule has identified some areas where we believe clarification or changes are needed to strengthen the process and ensure timely beneficiary access to care.

Overall, ACP is concerned about the unintended increase in administrative burden on physicians due to the provisions proposed in the rule. This program should be explicitly designed to avoid duplicative documentation and submission of information. **In addition, ACP encourages CMS to consider leveraging the use of health information technology (HIT) by physicians with this proposed prior authorization process.** HIT and electronic health records (EHRs) should be used to reduce administrative burden and complexity, making it possible for physicians to focus and spend more time on clinical care for their patients. **ACP also seeks clarification from CMS as to whether CMS considers DMEPOS ordering a responsibility of the primary care physician, or a responsibility of the ordering physician, which in many cases would not be the primary care physician.** Much of the recommendations and prescribing for these devices is done by subspecialty physicians who then ask the primary care physician to do the prior authorization. For example, a patient with a stroke or severe

arthritis may have particular physical findings that qualify the patient for a power wheelchair, and while this subspecialist has made this recommendation, has the relevant documentation, and has unique qualifications to answer questions as to why this device is needed as opposed to another device – the primary care doctor is typically expected to complete the paperwork. **In addition, ACP seeks clarification on whether the prior authorization requires a face to face encounter with the patient.**

ACP understands that CMS plans to have a list of initial items that would be included on the "Master List" of DMEPOS items that are frequently subject to unnecessary utilization using the two category approach. As proposed, the two criteria to determine if an item is included in the master list are (1) if an item has been identified in a GAO or HHS OIG report from 2007 or is identified later than 2007 as having a high rate of fraud or unnecessary utilization OR (2) if the item is listed in the 2011 or later CERT program's annual improper payment rate report for DME services. If an item meets one of these two criteria, it must also have an average purchase fee of $1000 or greater or an average rental fee schedule of $100 or greater to be included on the master list. **ACP is concerned that physicians are often unaware of the average purchase/rental prices associated with certain DMEPOS items, and given the cutoff price point which CMS has proposed, it is very likely that a different brand of the same item or a slightly different device may not need prior authorization. We would ask that CMS provides full and transparent information to the clinician and the patient at the time of ordering, such that the clinician and patient can jointly determine if a particular device is essential, if the patient's diagnoses and findings justify the device, and whether an alternative is available which may be less costly and does not require prior authorization. Furthermore, as many prior authorization requests arise not from a clinician determination, but an interaction between the patient and a DMEPOS sales representative, the clinician is typically faced with a Yes/No determination – without knowledge of costs or alternatives. Enhancing the information that is available to patient and doctor as part of the determination process is likely to result in lower costs for the same outcomes.** Increased transparency would help ensure appropriate patient education and affirmative prior authorization decisions, in order to provide timely care. That being said, physicians should not be expected to spend excessive professional time comparing cost of equipment, thresholds, criteria for prior authorizations, and the required documentation. ACP recommends that CMS investigate more streamlined processes such as developing an ordering process, perhaps through one central website, for all DMEPOS that only require answering a few questions before getting an approval or rejection in real time. CMS could also investigate developing a step wise schematic for providers, for determining the need for DMEPOS prior authorization on the basis of the patient's clinical issues and functional status that would guide providers to appropriate documentation and set the expectations with the patient. Such illustrated processes increase transparency in our system and can be used by physicians and staff to get the required documents, lessen the burden and also take away frustration from patients who often feel that the provider is the hindrance in their access to the medical equipment. In addition, ACP asks for clarification on time frame (i.e. weekly, monthly, or annually) in regards to the average purchase or rental fee.

ACP applauds CMS' proposal to not create any new clinical documentation requirements in the proposed process for implementing a prior authorization program. We would be supportive of CMS investigating whether the use of diagnosis codes and other existing documentation in the EHR could effectively demonstrate medical necessity - thus eliminating duplicative documentation requirements and reducing the administrative burden on physicians. The College is supportive of CMS ensuring that all necessary requirements are met *prior* to the item being furnished to the beneficiary, and before the claim is processed. In addition, the review/decision time period (both expedited and regular) proposed by CMS

seem reasonable. The College encourages CMS to monitor the impact this process has on patient access to care to ensure that it does not cause delays in necessary medical care. It will be especially important to monitor the impact that the review/decision time period has on inpatient care in cases where the patient is discharged before receiving the service or item. If extended delays in care and/or unintended consequences are found to exist, ACP urges CMS to shorten this time frame to make certain patients are receiving timely access to care.

The College encourages CMS to consider that chronic and/or lifelong conditions should not require the same authorization requirements as those that are not. **ACP recommends eliminating the need for a prior authorization for these types of items/services or developing a different and simpler process for these items/services that is less burdensome for the physician.** For example, documentation of a missing limb for prosthesis should not be required annually as a missing limb is a permanent condition and he or she will always need the prosthesis.

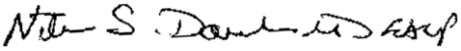
The College appreciates CMS' effort to reduce the post payment reviews, the burden associated with collecting money back from the physician, the time and cost involved in the appeals process, and the need for refunding of money to Medicare or the supplier. The current process is financially and administrative burdensome for many physician practices and can negatively impact the practice's flow of revenue and financial planning.

Although not directly related to the prior authorization process, ACP also notes that the use of "direct-to-consumer" advertising by DMEPOS suppliers has become a hindrance to the patient-physician relationship and places undue burdens on the physician and often leaves patients confused and misinformed. The decision and assessment of whether a patient needs particular medical equipment should be left to a clinical care team. **The College would appreciate a collaborative effort by CMS to address this concerning and growing issue.**

In summary, the College supports CMS' goal of ensuring beneficiary access to care and protecting the Medicare Trust Funds without placing undue burden on clinicians and suppliers. We thank you for the opportunity to comment and appreciate your effort to address this issue while taking into consideration the perspective of and impact on clinicians and patients.

Please contact Thom Kuhn, at tkuhn@acponline.org or 201-261-4500 if you have any questions regarding this letter or would like to request collaboration with the College to address the stated issues of concern.

Respectfully,



Peter Basch, MD, FACP
Chair, Medical Informatics Committee
American College of Physicians

Nitin Damle, MD, FACP
Chair, Medical Practice and Quality Committee
American College of Physicians