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- (1) Comments on Proposed/Draft LCD on Lower Limb Protheses (DL33787)
- (2) Comments on Proposed Comprehensive Care in Joint Replacement Rule, CMS-5516-P

We, the undersigned, share the privilege of having served in the past as Presidents of the American Association of Orthopaedic Surgeons (AAOS). We write, not in any official capacity with respect to that organization, but simply as colleagues who share serious concerns with respect to two recent rulemaking proposals under the auspices of CMS, both of which, if implemented, we believe would do serious harm to Medicare and the patients we serve.

First, the DME MACs have initiated a far-reaching proposal to change dramatically the Local Coverage Determination (LCD) regulations which determine which Medicare amputee beneficiaries are entitled to receive which type of prosthetic devices, and how Medicare will pay for the devices and related services in delivering those prosthetic limbs. There is much that is very negative about this proposal, and precious little that could be termed positive. The proposal is so far removed from the realities of the prevailing standard for care of these patients that it prompted us to inquire as to the specialty affiliations of the Medical Directors identified by the four private sector contractors Medicare has retained to help manage these matters. We find a general internist, a cardiologist, a rheumatologist and a family physician. We mention this not to question at all what are doubtless the eminent qualifications of these physicians in their chosen fields of training and practice, but to underscore that none of these specialties typically have any significant, sizeable involvement with the care and treatment of amputee patients. That is work that is more typically the province of physicians specializing in physical medicine and rehabilitation, vascular surgery, and orthopedic surgery. While it may not be considered germane to this LCD proposal, it would certainly make sense for CMS to consider the inclusion of one or more physicians from one of these three more 'amputee-focused' specialties for roles as the Medical Directors dealing with amputee/prosthetic issues.

When originally released, the proposed LCD was not accompanied by any scientific/medical/literature rationale or support, despite the fact that such science is a prerequisite requirement in the DME MAC's own published procedures relating to LCD content. Subsequently, it was noted that a bibliography had been inadvertently omitted, and a listing of 31 references—including articles in the lay press, text of proposed legislation never enacted and publications of the DME MACs themselves was included. By and large, the items listed in this bibliography do not relate to, and certainly do not support the very dramatic departures from standard of care posited in the proposal, and several of the authors whose works are referenced in that bibliography have been quick to assert that they cannot support either the LCD's proposed policies nor the use of their publications as germane to these proposals.

The things that are misguided and downright wrong about this proposal are too many for us to recount here. The proposal would radically change the long-standing K level descriptors that are central to criteria patients must meet to secure advanced prosthetic legs, and if this were done, it would be very confusing and have a very detrimental impact not only on patients, but also on physician prescriptions and patient outcomes. If enacted, this proposal would largely revert Medicare amputees to a 1970's standard of care. The proposal is wrong even about how to attain the most cost-effective care ignoring recent Medicare data which demonstrates that appropriate modern prosthetic care saves both time and money. It also would be offensive in perpetuating claim examiners delving ever deeper into physicians' records for information unrelated to patient mobility, scouring to find something to "justify" downgrading the Medicare beneficiary's care and reversing the recommendations of the physician who has actually seen, evaluated and treated Medicare's amputee beneficiary.

The policy would preclude availability of advanced prosthetics for patients who don't attain 'natural gait,' who have a record of having used an assistive device (cane, crutches, walkers or wheelchairs—even for nighttime bathroom access), and who have evidence of cognitive, cardio-pulmonary or neuro-muscular limitations. In truth, there is no rational justification why our patients who have asthma, take medications for hypertension or have some early stage dementia are not fully capable of being "community ambulators." It is hard not to perceive this proposal as a rationing scheme pure and simple.

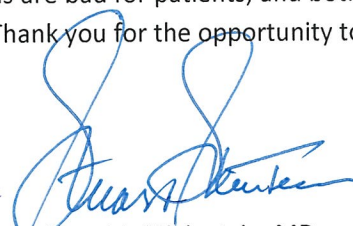
Turning to the CCJR proposed rulemaking, we oppose this proposal first and foremost because while Congress has considered various bills on the topic of post-acute care bundling, Congress has never either authorized or delegated to CMS the instructions to move forward with this type of bundling plan. While presented as an initiative from the Medicare Innovation Center, this is a mandatory program, and the 75 areas make its scope national. Essentially, this first step asserts that it would allow physicians and other providers to continue to be paid their current fees, but with the **hospitals to receive an incentive payment to the extent that the total of ALL fees from all providers for all services in the bundle come in under a set target** per joint replacement. If providers are paid the same amount per service, the only way the hospital could earn its bonuses is by driving down the number of services—in that respect this proposal poses a serious threat to the standard of care currently provided to Medicare beneficiaries. Once implemented, it will doubtless expand in two major ways—(a) more services will be included beyond just knees and hips; and (b) gradually CMS will move toward making the entire bundled payment to the hospitals who will bid out some or all of the other services. This is bad idea, another evidence of Medicare's seemingly insatiable desire to drive down Medicare costs by any means, even means that are clearly going to be detrimental to the Medicare beneficiaries that the system is supposed to serve.

Both of these proposed actions are bad for patients, and both should be rescinded as ill-fated forays into stripping back patient quality of care. Thank you for the opportunity to convey our concerns on these two proposals.

Very truly yours,



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