

THE ORTHOTIC AND PROSTHETIC ALLIANCE

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June 30, 2014

SUBMITTED ELECTRONICALLY: <http://www.regulations.gov>

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
CMS 1488-P
7500 Security Blvd.
Baltimore, Maryland 21244

Re: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2015 [CMS-1608-P]

Dear Administrator Tavenner:

On behalf of the Orthotic & Prosthetic Alliance (the O&P Alliance), a coalition of the five major national orthotic and prosthetic organizations representing over 13,000 O&P professionals and 3,575 accredited O&P facilities, in conjunction with the Amputee Coalition, the nation's consumer organization representing persons with limb loss, we write to urge CMS to withdraw its proposal to remove a number of codes related to amputation from the presumptive compliance methodology related to the so-called "60 Percent Rule" applicable to Inpatient Rehabilitation Hospitals and Units ("IRFs").

In the FY 2015 IRF Prospective Payment System proposed rule, CMS states that it intends to remove ten ICD-9-CM diagnosis codes¹ that are status post-amputation diagnosis codes and two impairment group codes ("IGCs")² from the list of codes and IGCs that are presumptively compliant with the 60% Rule for IRF classification. With respect to the diagnosis codes, or "V" codes, CMS indicates that the ten codes do not satisfy the premise underlying the use of presumptive compliance, which is that a particular code represents a diagnosis that, if applicable to a given patient, more than likely means the patient required intensive rehabilitation services in an IRF for one of the 13 qualifying conditions or that the patient had a comorbidity

¹ V49.65 – Below elbow amputation status; V49.66 – Above elbow amputation status; V49.67 – Shoulder amputation status; V49.73 – Foot amputation status; V49.74 – Ankle amputation status; V49.75 – Below knee amputation status; V49.76 – Above knee amputation status; V49.77 – Hip amputation status; V52.0 – Fitting and adjustment of artificial arm (complete) (partial); and V52.1 – Fitting and adjustment of artificial leg (complete) (partial).

² IGC 0005.1 – Unilateral upper limb above the elbow, and IGC 0005.2 – Unilateral upper limb below the elbow.

that created such a requirement for IRF care. Similar reasoning is provided for the removal of the two IGC codes related to amputation.

With respect to eight of the V codes proposed for removal, CMS' assertion that the codes do not satisfy the criteria for applying presumptive compliance is incorrect. The V codes are all related to a patient's status post-amputation, with the first eight representing a diagnosis of status post-amputation of part or all of a limb.³ "Amputation" is listed as one of the 13 qualifying conditions for IRF classification under 42 C.F.R. § 412.29(b)(2). Therefore, it is appropriate to treat IRF admissions with the eight V codes relating to status-post amputation (when listed as a primary diagnosis in particular) as presumptively compliant and counting towards meeting the 60% Rule's threshold for IRF classification. CMS' proposal, with respect to these eight V codes, is contrary to existing regulations and should not be implemented.

As with the removal of the V codes from the presumptive compliance methodology, the removal of the upper extremity amputation IGCs (0005.1 and 0005.2) is also contrary to existing regulations. Again, amputation is listed as one of the 13 qualifying conditions for IRF care. Therefore, it is appropriate to treat IRF admissions falling within these IGCs as presumptively compliant and appropriately counted toward satisfaction of the 60% Rule's threshold for IRF classification.

If the proposed rule is finalized in its current form, it would create a substantial chilling effect on IRF admissions of patients with limb amputations, a serious condition post injury or illness that routinely requires comprehensive rehabilitation and close medical supervision. The fact that amputation has been included in the "CMS-13" (and its predecessor, the "HCFA-10") since the early 1980's when this list of typical IRF admissions was established, is compelling evidence that these codes should continue to satisfy the presumptive compliance standard under the 60% Rule.

The proposed changes to the presumptive compliance methodology in the FY 2015 IRF PPS proposed rule repeatedly violate the intention that patients with one of the 13 qualifying conditions for IRF classification, including amputation, arthritis, and lower extremity joint replacement ("LEJR"), be counted towards satisfying the 60% Rule threshold. This places a great burden on physicians responsible for IRF admission decisions, and IRFs in maintaining their classification, with the choice between declining to admit patients that do not meet the greatly restricted diagnosis codes and IGCs that remain presumptively compliant or undergoing full medical review in order to prove that the 60% Rule was satisfied.

In addition to being contrary to the existing regulations, CMS' proposed removal of the amputation diagnosis codes and IGCs from the presumptive compliance methodology is extremely concerning from a patient care perspective. CMS' targeting of amputation codes for

³ The remaining two V codes relate to fitting and adjustment of an artificial limb necessitated by an amputation. We acknowledge that these V codes alone are not more than likely to indicate that a patient required rehabilitation services at the intensity of that available in an IRF for purposes of determining presumptive compliance.

restriction is particularly concerning as it impacts a highly vulnerable population—patients who are status-post amputation. The medical judgment of the physicians treating patients with amputations (who, among the Medicare beneficiary population, have the potential to be significantly impaired already) should be the key factor in determining whether a patient is admitted to an IRF for intensive rehabilitation care.

In fact, a recent study comparing the outcomes for patients requiring rehabilitative care who are treated in an IRF versus a skilled nursing facility showed that the mortality rate for patients with amputations was significantly decreased in the IRF setting, with a 12% difference and 78 additional average days of life for patients receiving IRF care, and the average length of stay being almost 16 days shorter.⁴ Thus, CMS' proposal to restrict the presumptive compliance of patients with amputations, likely leading to reluctance on behalf of rehabilitation physicians and IRFs to admit such patients, may have a significant negative effect on amputees' health outcomes.

As professional and consumer organizations that work intimately with amputees, we strongly disagree with these proposals and respectfully urge CMS to continue recognizing amputation cases associated with the codes and IGCs proposed for removal as representative of the type of conditions that should be included in the presumptive compliance methodology for assessing a facility's satisfaction of the 60% Rule's threshold for IRF classification.

From experience, we know that patients dealing with the effects of limb amputation need frequent monitoring by a physician, prosthetist, and physical therapist to address the myriad issues, which include medical management during recovery and healing, residual limb pain (instruction and training on applying and maintaining graduated external compression on the amputation residual-limb to prevent debilitating post-operative edema), skin integrity, physical therapy in maintaining range-of motion of knee & hip joints, early prosthetic fitting, phantom limb pain management, and, eventually, prosthetic limb fitting and gait training (including critical postural balance, and relative mobility-related daily activities to optimize function as early as possible – thereby avoiding contractures and immobility, assuring safety), as well as prosthetic adjustments and prosthetic training as the patient progresses through the rehabilitation process. Proper fitting and training in the use of a prosthesis by new amputees is complex and requires close supervision of a prosthetist, physician, nursing, and therapy – often times at a level that is not consistently available in other non-IRF care settings.

Furthermore, critical medical care provided by medical personnel with specialized training in rehabilitation can make much difference in the health and functional outcomes of patients with amputations by addressing the patient's post-amputation capabilities/deficiencies and outlining a treatment plan to maximize mobility; residual limb healing and care; physical therapy to maintain function of strength, range of motion and balance; occupational therapy to

⁴ DaVanzo JE, Dobson A, El-Gamil A, Li JW, and Manolov N. Assessment of patient outcomes of rehabilitation care provided in inpatient rehabilitation facilities after discharge. 2014. Materials available at: http://www.amrpa.org/Newsroom/Final_Dobson_DaVanzo_Report.pdf.

teach adaptations and safe use of adaptive equipment; and hands-on training during the initial fitting and use of prosthetic limbs. Even if a prosthesis is not provided to a patient during the IRF stay, the adaptation to amputation, coping and functional skills development, and prosthetic fitting and training that occurs in such settings is critical. Rehabilitation provided in IRFs allows patients to reach their full functional potential, maximizing the patient's physical and psychological comfort with his or her new status as a person with limb loss, and accurately assessing what the patient's functional capacity may be – and thereby reducing or eliminating late effect complications.

The academic evidence base continues to grow that demonstrates that an IRF level of care greatly improves amputee health and functional outcomes across the board. In a 2008 study, researchers examined more than 2,600 veteran amputees who underwent either transtibial (below the knee) or transfemoral (above the knee) amputations and found that the majority of these patients were prescribed inpatient rehabilitation.⁵ Adjusting for selection bias, the study focused on the benefits to lower-limb amputees receiving inpatient rehabilitation versus those who received no inpatient rehabilitation. The study results showed clear benefits for patients receiving inpatient rehabilitation.

First, patients receiving inpatient rehabilitation following their amputation were 1.51 times more likely to survive. Second, inpatient rehabilitation amputees were 2.58 times more likely to be discharged directly home (instead of to another post-acute care setting). These results suggest that ongoing reductions in the availability of rehabilitation services could have “tangible and detrimental effects” on patient health.⁶

In April 2013, a multi-center longitudinal study measuring the effects of inpatient rehabilitation on amputee patient functional outcomes was conducted.⁷ The study measured physical functioning and impairment in activities of daily living six months after the amputation procedure for amputees in three different post-acute settings: IRFs, skilled nursing facilities (“SNFs”), and at home. Forty-three percent of the amputee subjects received their post-acute care at an IRF, 32% at a SNF, and 24.6% at home. (Nearly 75% of all the amputees were Medicare beneficiaries.)

The results of the 2013 study showed significantly improved outcomes for IRF amputee patients versus SNF amputee patients in physical function, role limitations due to physical problems, and overall physical component scores, with generally improved outcomes in general

⁵ See Stineman et al. The effectiveness of inpatient rehabilitation in the acute postoperative phase of care after transtibial or transfemoral amputation: study of an integrated health care delivery system. ARCH. PHYS. MED. REHABIL., 2008 Oct; 89(10): 1863–72.

⁶ Stineman et al., *supra* note 5, at 1870.

⁷ Sauter CN, Pezzin LE, and Dillingham TR. Functional outcomes for persons undergoing dysvascular lower extremity amputations: effect of a post-acute rehabilitation setting. AM. J. PHYS. MED. REHABIL., 2013 April; 92(4): 287–96 (NIH Public Access Author Manuscript edition).

health.⁸ In their discussion of these results, the researchers noted that the across-the-board benefits for lower-limb amputee patients in IRFs confirm findings from past retrospective analyses that show a positive association between IRF care and other health-related outcome measures for Medicare dysvascular lower-limb amputation patients, such as lower re-amputation rates, greater medical stability, and improved prosthesis acquisition.⁹

The researchers also opined on the causes of better outcomes in IRFs, citing as possible causes the close monitoring for post-operative complications, daily physiatrist and rehabilitation nursing visits, coordinated discharge planning via individual meetings, and focused goal-setting, as well as the intense focus in IRFs on self-care training, family transition education, and early post-operative mobility.¹⁰ The researchers also noted that the frequent interaction with a rehabilitation psychologist in an IRF or inpatient rehabilitation unit may also have a positive impact on functional outcomes.¹¹ The study highlighted that, in contrast to these offerings in IRFs, SNF care is frequently less intense and encompasses less medical oversight.¹²

Based on these studies and our own patient care experiences, we believe that CMS' proposal to eliminate any amputation cases from the presumptive compliance methodology inadequately accounts for the important patient-centered benefits associated with IRF care for this patient population and will ultimately impede access to IRF benefits for many amputation patients. The collective effect of CMS regulations in this area has been to push IRFs toward the far more onerous process of medical review and force IRFs to significantly restrict the types of patients they can admit so as to avoid potentially jeopardizing their IRF classification.

Requiring the level of medical review that will be necessary if large numbers of IRFs no longer meet the presumptive compliance threshold will bog down the classification process, endangering access to inpatient rehabilitation. This places a great burden on physicians responsible for IRF admission decisions, and IRFs in maintaining their classification, with the choice between declining to admit patients that do not meet the greatly restricted diagnosis codes and IGCs that remain presumptively compliant and undergoing full medical review in order to prove that the 60% Rule was satisfied.

CMS' proposed changes would have the effect of chilling access to inpatient rehabilitation for vulnerable patients with amputations that need the intensive and hands-on care available in such settings to fully reach their post-amputation potential. Therefore, CMS should reconsider and reject its proposed restrictions on the presumptive compliance methodology under the FY 2015 IRF PPS proposed rule.

⁸ *Id.* at manuscript 7.

⁹ *See, e.g.*, Dillingham TR, Pezzin LE, and Shore AD. Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations. *ARCH. PHYS. MED. REHABIL.*, 2005; 86:480–86.

¹⁰ Sauter et al., *supra* note 7, at manuscript 9.

¹¹ *Id.*

¹² *Id.*

To contact the O&P Alliance directly, please call Peter Thomas, O&P Alliance Counsel, at your convenience at 202-872-6730 or email Peter.Thomas@ppsv.com. Thank you for your consideration of our views.

Sincerely,



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