October 9, 2014

Dr. Charles Haley
Medicare Contractor Medical Director
Noridian Healthcare Solutions
900 42nd St. S
Fargo, ND 58108-6747

Dear Dr. Haley:

Thank you for your prompt response to our concerns regarding the recent Noridian coverage article on hemodialysis frequency.

We appreciate that you have made a small change in the article to remove the phrase regarding the one additional session per month limitation; however, other significant issues remain with the coverage article. Your statement that "there is nothing new here" is simply not supported by the facts. The article introduces significant new restrictions on medical justification codes, the requirement of a new modifier, and a blanket prohibition on billing for "daily" dialysis, regardless of medical necessity, in contradiction to stated CMS policy on payment for more frequent hemodialysis sessions with medical justification.

These significant changes, if implemented, will restrict access to therapy that is medically justified by the prescribing physician, and that is in accordance with long-standing Congressional intent to encourage adoption of home dialysis. It is also contrary to CMS regulations on policy changes to implement any such payment restrictions without a proper LCD process, which would otherwise require a 45-day comment period and a 45-day notice period.

The statement that "Medicare only pays for three hemodialysis sessions per week regardless of what the patient's prescription actually is" is untrue. Medicare's policy, as carried out by the MACs, has consistently been to reimburse ESRD facilities based on three hemodialysis treatments per week and allow the payment for additional dialysis treatments with medical justification. CMS has reiterated this policy many times, including in the final rule that initially

implemented the bundled payment system[1], the Medicare Benefit Policy Manual (updated 12/2013)[2], the Medicare Provider Reimbursement Manual (updated 12/2013)[3], and the even the most recent proposed rule addressing 2015 payments.[4]

In the 2012 final rule, CMS acknowledged the greater prevalence of more frequent hemodialytic therapies in the home setting, as well as the growing body of clinical literature supporting the medical necessity of more frequent sessions. CMS stated "[W]e are aware that there are observational studies that support additional weekly dialysis treatments and that there is some industry support for additional treatments. We have and will continue to monitor and analyze the number of dialysis treatments that Medicare beneficiaries receive to determine whether a change in this longstanding policy is warranted."[5] Clearly CMS was not only aware that facilities were being paid for more than three sessions per week, but it publicly acknowledged the practice and explicitly elected not to change the longstanding policy.

Your response also draws an arbitrary distinction between services routinely prescribed for patients and additional sessions outside the prescription. CMS makes no such distinction. Noridian's approach is inconsistent with the clearly stated rationale in the 2010 final rule for establishing the hemodialysis session as the unit of payment, stating that this best achieves "the effect of the bundled payment system without adversely impacting beneficiary access to home dialysis services." More importantly, Noridian is effectively stating that when more frequent hemodialysis is prescribed for patients routinely, it is never medically justified. That position forecloses the ability of a provider to have claims assessed under the medical justification standard in the CMS manuals, when it submits those claims based on physician prescription, medical record documentation, and beneficiary clinical status – criteria previously indicating that medical justification had been supported. This is adverse to CMS policy stating, "The only time facilities should seek payment for additional dialysis sessions, including payment for shorter, more frequent modalities, is when the patient has a medical need for additional dialysis and the facility has furnished supporting medical justification for the extra treatments."[6]

Finally, the article is not clear as to whether the listed diagnosis codes represent an exclusive list of the conditions that will support the payment of additional dialysis sessions by Noridian beginning on October 10th. As you are aware, Noridian has been paying for medically justified additional sessions with conditions beyond those captured by the diagnosis codes listed in the coverage article (as evidenced in our analysis of payment history with Noridian for more

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[1] 75 Fed. Reg. 49030, 49137 (Aug. 12, 2010) ("with medical justification, payments will continue to be made for additional treatments required beyond the usual three per week under the ESRD PPS").
[2] Medicare Benefit Policy Manual, Ch. 11, § 50 ("Regardless of dialysis modality or treatment setting, payments for additional treatments may be made when they are medically justified. The FI or A/B MAC reviews the medical justification and is responsible for making the decision on the appropriateness of the extra treatment").
[3] Provider Reimbursement Manual, Part I, § 2709 ("Claims for hemodialysis furnished more frequently than three times per week must be accompanied with medical documentation explaining the reasons for the additional dialysis sessions").
[4] 79 Fed. Reg. 40208, 40233 (Jul. 11, 2014) (since the 1980s, CMS has "allowed for the payment of additional weekly dialysis treatments with medical justification").
[5] 77 Fed. Reg. 67450, 67469 (Nov. 9, 2012).
[6] Id.

frequent hemodialysis). Noridian should be clear that the listed ICD-9 (or -10, as the case will soon be) codes are not the only codes representing conditions for which medical justification supports additional sessions. And, if it wishes to implement new guidance regarding codes that will never be paid in certain circumstances, Noridian must follow the appropriate LCD process established for such payment restrictions.[7] For your reference, we have included a listing of some of the codes used in support of payment received from Noridian historically for additional sessions of hemodialysis.

To clarify, we are in no way asking that Noridian "exempt home dialysis from Medicare's dialysis payment policy." Quite the contrary, we are asking that payment for medically justified more frequent therapy be treated consistently with historical CMS policy, regardless of setting. We strongly believe that Noridian is not in a position to deviate from the application of the medical justification standard in the CMS manuals or the per treatment unit of payment maintained after the implementation of the new bundled payment system. Noridian's specific statements about extra payment for home hemodialysis patients also are not consistent with past CMS statements, such as in the initial ESRD PPS final rule, where CMS reiterated its goal of increasing home dialysis. Furthermore, the implied restriction of payment for codes from what has historically constituted medical justification to support payment does not follow the appropriate process for making such changes.

Importantly, we are not aware of any evidence of overutilization of medically justified more frequent dialysis sessions, particularly involving home hemodialysis (itself, under 2% of the ESRD patient population).

Thank you again for your correspondence on this coverage article. The article has an effective date of October 10, 2014. Because of the significant changes being implemented, we ask that it either be withdrawn, or revised consistent with the above suggestions, as soon as possible, and certainly before the October 10, 2014 implementation date. In addition, we request a face-to-face meeting with Noridian so that we may share our current practices and discuss policies going forward.

Sincerely,

Stephanie Silverman
Executive Director

Cc: Tom McGraw (Noridian CEO), Paul O'Donnell (SVP JE), Emy Stenerson (SVP JF)

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[7] See Medicare Program Integrity Manual, § 13.4.A "Contractors shall develop LCDs when they have identified an item or service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review."

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