August 30, 2013

Laurence Wilson
Director, Chronic Care Policy Group
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Wilson:

On behalf of the members of the American Clinical Laboratory Association ("ACLA"), many of whom provide services to end stage renal disease ("ESRD") beneficiaries on renal dialysis, I am writing to express our concerns about post-regulatory issuances by the Centers for Medicare and Medicaid ("CMS") that deviate from a published and clearly defined list of laboratory tests that are included in the ESRD prospective payment system ("PPS"), and which raise confusion about whether the lab list (designated as Table F in the 2010 ESRD PPS Final Rule) remains the definitive guidance on which laboratory tests are included in, and excluded from, the ESRD PPS. For example, on June 7, 2013, CMS published Transmittal 171, CR 8261 (the "Transmittal") with the stated purpose "to update and reorganize the ESRD chapter in the Medicare Benefit Policy Manual to reflect the ESRD PPS." As discussed herein, ACLA believes that several provisions in the Transmittal constitute new or significantly revised CMS policy with regard to laboratory services included in the ESRD PPS, and that such new and revised policy changes were issued outside of the rulemaking process, and without opportunity for notice and comment.

From a historical perspective, when the composite rate was first enacted in 1981, the per treatment rate included payment for a number of clinical laboratory tests commonly performed for ESRD beneficiaries on renal dialysis. The composite rate lab panel consisted primarily of chemistry and hematology tests to monitor the adequacy of the dialysis treatment and to treat the comorbid conditions of mineral metabolism disorders and anemia of ESRD that commonly result from renal failure. CMS developed a series of complex lab billing rules to prevent separate payment when a panel of chemistry tests included a majority that were already in the composite.

Due to the chronic and complex nature of many patients with ESRD, a number of additional lab tests are often ordered and drawn during dialysis to monitor and treat clinical conditions that are not related to the treatment of ESRD. All other lab tests that were ordered for ESRD beneficiaries remained separately billable if the tests were a covered serviced and determined by Medicare to be reasonable and necessary, and if justification of medical necessity was provided. CMS later issued national coverage policies that permitted payment for several additional commonly performed laboratory tests with medical justification based solely on the diagnosis of ESRD. Clearly, with respect to lab testing for beneficiaries on renal dialysis and in view of newly developed lab tests and changes in nephrology practice, CMS generally recognized the need for periodic changes to payment for lab services for ESRD beneficiaries, and revised or adopted ESRD lab-related policies accordingly.

Laboratory Tests in the ESRD PPS

When the ESRD PPS was implemented, consistent with the requirement under MIPPA, CMS properly included diagnostic laboratory services that are "furnished for the treatment of ESRD."[1] The ESRD PPS Final Rule in 2010 contained Table F ("CMS-1418-F"), which lists the laboratory tests that were purported to be included in the ESRD PPS. The all-inclusive nature of Table F is clearly established in the ESRD PPS final rule. In fact, the preamble to the rule specifically states that "[t]he ESRD related laboratory tests that will be subject to the ESRD PPS are identified in Appendix Table F of this final rule."[2] The rationale for CMS' position is articulated in the following comment and response from the 2010 rule:

> **Comment:** Several commenters recommended that we include in the ESRD PPS payment bundle only those laboratory tests that are generally furnished for the treatment of ESRD, and included lists of approximately 50 tests which they believe account for about 95 percent of the laboratory tests ordered by ESRD facilities for ESRD patients. The commenters pointed out that such specificity would leave no doubt as to whether a particular laboratory test would be included or excluded from the payment bundle…
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> **Response:** We agree with the commenters that limiting the laboratory tests for payment under the ESRD PPS payment bundle to specific tests that are customarily performed in connection with the treatment of ESRD comports with section 1881(b)(14)(B)(iv) of the Act and would be a straight forward method of capturing only ESRD-related laboratory testing… Therefore, in order to develop a list of ESRD-related laboratory tests, we identified those laboratory tests that were most frequently identified on the lists we reviewed. Then, we received input from physicians working with UM–KECC. Lastly, CMS physicians and other clinical staff finalized the list which is contained in Table F of the Appendix.[3]

A similar discussion appears later in the rule, where CMS again states "[w]e agree with the commenters there should be a specific list identifying laboratory tests that are furnished for ESRD patients" and that the resulting list compiled by the agency and presented at Table F are tests that are "covered under the ESRD PPS bundled payment."[4] CMS also indicates that it will "monitor claims to see if additional laboratory tests should be added" to the Table F list.[5] The CY 2012 proposed rule also reiterates that the CY 2011 final rule "finalized a specific list of routine ESRD-related laboratory tests included as part of consolidated billing."[6]

ACLA strongly supported the establishment of a clearly defined list of laboratory tests for a number of reasons. We appreciated the thoughtful and deliberative process by which CMS developed this list, and we agreed that the lab tests on Table F were (and are) consistent with the statutory requirement under MIPPA to include in the ESRD PPS diagnostic laboratory tests that are "furnished for the treatment of ESRD." Finally, we believed, and continue to believe, that it is critically important for dialysis providers and ordering practitioners to have a complete

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[1] PUBLIC LAW 110–275—JULY 15, 2008
[2] 75 Fed. Reg. 49029, 49055
[3] 75 Fed Reg. at 49054 (emphasis added)
[4] Id. at 49169 (emphasis added)
[5] Id.
[6] **Federal Register** / Vol. 76, No. 131 / Friday, July 8, 2011

understanding of items and services that are either included in, or excluded from, the ESRD PPS. We believed that the absence of such specificity would create uncertainty and chaos, leaving ordering practitioners and dialysis facilities to their own discretion to determine whether a lab test is "furnished for the treatment of ESRD." With no clear guidance, such individual decisions would vary greatly, with no real consensus.

The creation of a list of laboratory tests included in the ESRD PPS avoided such potential confusion. In fact, CMS specifically stated in the 2010 final rule that among the benefits of having a defined list of bundled tests is that "ESRD facilities can use this list in developing contractual relationships with laboratories," which is precisely what occurred in the months after the rule was finalized.[7] We believe the 2010 ESRD PPS final rule is absolutely clear that Table F tests reflect all of the clinical laboratory services in the ESRD payment bundle, with CMS retaining the ability through notice and comment rulemaking to revisit and revise the list periodically.

Increasing Confusion about Laboratory Tests in the ESRD PPS

What CMS has not done until the Transmittal is to state that any laboratory test that may be ESRD-related is subject to the ESRD PPS, whether or not that test is included on the list of "Labs Subject to Consolidated Billing," which is included as a link in the Transmittal. Avoiding uncertainty about which tests are included in, and excluded from, the ESRD PPS remains an important issue for ESRD facilities, ordering practitioners and clinical laboratories. However, in the past few years we have observed that ESRD lab-related post-regulatory guidance issued by CMS, including the Transmittal, contain language which raises the very concerns and confusion that we had hoped would be avoided. Specifically, we believe that such guidance deviates from the clearly defined ESRD PPS lab list in a way that makes it unclear about whether the lab list remains the definitive guidance on which laboratory tests are included in, and excluded from, the ESRD PPS.

New Requirement for Practitioner Determination of ESRD-Related Lab Tests

The recently revised Medicare Benefit Manual Policy[8] (the Transmittal) contains the following provision:

> The distinction of what is considered to be an ESRD-related laboratory test is a clinical decision determined by the ESRD patient's ordering practitioner. If a laboratory test is ordered for an ESRD-related condition, then the laboratory test is considered to be a renal dialysis service and is not paid separately. [9]

The statements in this Transmittal imply that for every laboratory test ordered for an ESRD beneficiary, the ordering practitioner is required to determine on an individual test-by-test basis whether the lab is "ESRD-related." As stated above, this deviates from the intended purpose of the carefully developed laboratory list, and leaves practitioners with no guidance as to the definition of "ESRD-related," which, again, should be stated as "furnished for the treatment of ESRD."

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[7] 75 Fed. Reg. at 49169
[8] Change Request 8262 - June 7, 2013
[9] Id at § 20.2

Some practitioners might take the position that *any* lab test ordered incident to the dialysis treatment is "ESRD-related," while others might believe that only lab tests ordered to monitor and treat the very limited and specific conditions caused by renal failure fall into this category. Still others might take the position that CMS has already given clear guidance on this by issuing Table F, which is widely accepted as the list of laboratory tests that meet the statutory definition of "furnished for the treatment of ESRD." Again, leaving such determinations to the discretion of individual practitioners will have the effect of causing a great deal of confusion, inconsistent billing practices and potential overuse of the AY modifier.

As stated, ACLA believes that several provisions in the Transmittal constitute new CMS policy or significant changes to CMS policy with regard to laboratory services included in the ESRD PPS, and that such new policy and significant policy changes were issued outside of the rulemaking process and without opportunity for notice and comment.

Lipid Panel Improperly Included in ESRD PPS

The lipid panel (CPT Code 80061) was added to the ESRD PPS through a change request and without proper notice and opportunity for comment. That change[10] stated: "[b]ecause organ disease panels consist of AMCC laboratory tests that are ESRD-related laboratory services, it is important for CMS to *ensure that these laboratory tests remain in the ESRD PPS bundle*."[11] *None* of the three components of the Lipid Panel - cholesterol, triglycerides, high density lipoprotein ("HDL") were determined to be "furnished for the treatment of ESRD" by the deliberative group that developed the original list of lab tests, and these lipid tests were not included in the Table F of the 2010 ESRD PPS Final Rule. Other organ and disease panels that were added to the ESRD PPS also contain some test(s) that were not included in the original lab list. In their 2012 Final Rule, CMS clarified the inclusion of the lipid panel in the ESRD PPS by giving one example of when a lipid test might be related to ESRD, and stated that: "if the Lipid Profile laboratory test is furnished for reasons other than for the treatment of ESRD, the laboratory service may be billed with the AY modifier and are eligible for separate payment."

CMS did not clarify whether it is the entire panel that is included in the PPS, and whether the individual tests are properly billable if ordered individually. In any event, and of greater concern, physicians have opined that even if it can be reasonably argued that a lipid abnormality *might* be indirectly related to the beneficiary's modality of peritoneal dialysis (the example given by CMS in their 2012 Final Rule clarification), this situation would account for a mere fraction of lipid test orders, as the majority of lipid test orders are related to the monitoring and treatment of *cardiovascular disease, not ESRD*. Thus, CMS guidance on using the AY modifier puts the dialysis facility (and the contracted laboratory) in the position of *using the AY modifier for the vast majority of lipid test* to justify payment as they are not furnished for the treatment of ESRD. Had the renal community been given the opportunity to articulate its position and concerns about adding lipid testing prior to the inclusion of these tests in the ESRD PPS through appropriate notice and comment rulemaking, this situation could have been avoided.

Inconsistent Terminology to Describe Laboratory Tests in the ESRD PPS

To add to the confusion, CMS is inappropriately using various terms to describe items and services that are included in the ESRD PPS. Throughout various rules and guidance documents,

[10] Change Request 7497, January 2012
[11] Id. (emphasis added)

CMS has used the terms "renal-related," "ESRD-related," and "furnished for the treatment of ESRD" interchangeably. We believe this mix of terms is inappropriate and may be in conflict with the specific statutory requirement to include in the ESRD PPS clinical laboratory services that are "furnished for the treatment of ESRD."

The term "renal-related" is a much broader term than either of the other terms used, and may apply to a wide array of items or services for a patient with any renal condition that may have nothing to do with ESRD. To a lesser extent but still noteworthy, "ESRD-related" is broader than "furnished for the treatment of ESRD" because one can imagine that almost any pathologic derangement that is found to be *slightly more prevalent* in ESRD patients (e.g. low testosterone) could conceivably be "related to ESRD," albeit very loosely so. However, conventional views do not dictate that treatment for "low testosterone" with supplemental hormone is treatment that is "furnished for the treatment of ESRD" per se.

Concerns about Post Payment Audit Liability

The dialysis facility's contracted clinical laboratory is the entity that submits claims to Medicare for laboratory tests outside of the bundle, thus, the laboratory is essentially put at risk for claim denials and post payment audit liability for differences in opinion (auditor v. practitioner) about whether a particular test should be broadly or narrowly viewed as being "ESRD-related." This is an untenable position for the laboratory, which is why the industry argued in its comments on the initial ESRD Proposed Rule – a position with which CMS agreed – for the certainty of a definitive list of laboratory tests that are included in the ESRD PPS.

While it is relatively easy to identify situations where tests included on the lab list tests may be ordered for reasons unrelated to the treatment of ESRD, that distinction can be much more difficult to make, in some cases, for other tests outside of the bundle. For these latter tests – that is, the tests <u>not</u> included on a defined lab list – whether they could be viewed in any given case as being "related to" the treatment of ESRD is a question that can be answered either broadly or narrowly.

Additional/Revisions to Lab Tests in the ESRD PPS

CMS also indicates that it will "monitor claims to see if additional laboratory tests should be added" to the lab test list.[12] The frequency of lab test orders is not the sole determinant of whether a test is "furnished for the treatment of ESRD." A number of lab tests that are commonly performed for ESRD beneficiaries are ordered to monitor and treat clinical conditions that are unrelated to ESRD. Such tests were properly and, apparently intentionally, excluded by CMS from the Table F lab list in the first ESRD PPS Final Rule. As a more reasonable approach, ACLA recommends that CMS implement a process for periodic review of current nephrology clinical practices to determine whether it is appropriate to amend the lab tests included in the ESRD PPS, adjust reimbursement appropriately, and propose any changes through notice and comment rulemaking. This process should include input from various stakeholders with expertise in standards of clinical care for ESRD beneficiaries.

ACLA strongly urges CMS to take the following actions:

- Clarify that the *only* clinical laboratory tests included in the ESRD PPS are those CPT codes listed on the list of "Labs Subject to ESRD Consolidated Billing";

[12] Id.

- Implement a periodic review process that includes various stakeholders to evaluate current standards of clinical care for ESRD beneficiaries, including new lab tests that may be determined to be furnished for the treatment of ESRD;

- Consistent with requirements under the Administrative Procedure Act, follow notice and comment rulemaking procedures when seeking to issue changes or additions to items and services in the ESRD PPS;

- Remove uncertainty and requirements for ordering practitioners to determine on a test-by-test basis what is considered to be furnished for the treatment of ESRD, and revise guidance documents accordingly; and

- Revise manual guidance to be consistent with the statutory requirement that clinical laboratory tests in the ESRD PPS are "furnished for the treatment of ESRD," and eliminate terms such as "ESRD-related" and "renal-related"

Conclusion

ACLA urges CMS to remove any uncertainty regarding tests included in the ESRD PPS by confirming that only those CPT codes listed in the list of Labs Subject to ESRD Consolidated Billing are included in the ESRD PPS bundle. Any additional tests determined through review of current nephrology clinical practices that are furnished for the treatment of ESRD should be subject to notice and proposed rulemaking and not left to the determination of individual ordering providers. We would like to meet with you to discuss our concerns in more detail and will be following up with your office on this request.

Sincerely,

JoAnne Glisson
Senior Vice President

cc: Michelle Cruse
Stephanie Frilling