



February 21, 2020

**Via Electronic Mail Only**

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services (CMS)  
200 Independence Avenue SW  
Washington, DC 20201

Dear Administrator Verma:

The Advanced Medical Technology Association (AdvaMed) applauds CMS's decision to establish the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)<sup>1</sup> in the final CY 2020 Medicare End-Stage Renal Disease Prospective Payment System (ESRD PPS) Final Rule. We are sending this letter to recommend four specific modifications to the TPNIES Program that we urge CMS to consider as the agency develops its policy approach to this year's ESRD PPS proposed rule. Our recommendations below address the length of the TPNIES add-on, inclusion of capital equipment, MAC implementation of the add-on, and appeals.

**Extend TPNIES Eligibility to at Least Three Years**

AdvaMed recommends that CMS extend the TPNIES adjustment period from two years to at least three years. CMS has expressly stated that the basis for the TPNIES payment adjustment is to enable and support the adoption of new technologies in the ESRD continuum of care, and we wholeheartedly agree. In its current form, the ESRD PPS Final Rule requires providers to cover the incremental cost of using new technologies under the existing ESRD PPS bundled rate at the conclusion of the two-year TPNIES period. However, based on our experience with other payment adjustments for new technology, two years is simply an inadequate amount of time after taking into account the scale of resources and time necessary to build a responsible support and distribution infrastructure nationwide. This is especially true for companies in their earlier stages.

Because the companies that frequently bring new and innovative equipment and supplies to market are smaller, they tend to lack the type of distribution and support infrastructure that their larger, more established counterparts may feature. Furthermore, staffing constraints of smaller manufacturers mean that most ESRD facilities would only have several months of TPNIES coverage by the time a smaller company could make the technology available to them. Accordingly, a two-year runway still leaves a level of risk that could discourage smaller start-up

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<sup>1</sup> See 84 Fed. Reg. 60648 (Nov. 8, 2019) ("ESRD PPS Final Rule").

companies from pursuing the development of new and innovative equipment and supplies. Extending the coverage period would help small innovators take full advantage of the TPNIES program.

### **Include Capital Assets in TPNIES**

We recommend that CMS treat capital-related assets (such as dialysis machines and water purification systems) as eligible items under the TPNIES program. Capital-related assets are critical components of ESRD care where innovation still lags. Incentivizing innovation in this area of the ESRD care continuum will produce meaningful improvements in clinical outcomes and patient experience because the success of new and innovative equipment and supplies necessarily relies on the performance of capital assets. By expanding TPNIES eligibility to include capital-related assets – regardless of how these assets are purchased by the provider – would enable greater investment in a broader array of new technologies that can improve care for ESRD patients.

Including capital equipment in the TPNIES could be accomplished by leveraging the amortization formula to calculate a per-minute cost for capital equipment used by physicians in the Medicare Physician Fee Schedule. The per-minute amount would be multiplied by the number of assumed minutes used per treatment, and then combined with several other inputs to calculate the Practice Expense Relative Value Units. CMS could use a similar methodology to determine a per-treatment cost for new dialysis capital equipment. Applicants for an add-on payment for dialysis capital equipment would supply the price and assumed life, and CMS would use standard inputs for the remaining elements using the same interest rate and useful life data values set forth in the Physician Fee Schedule.

### **Instruct MACs to Provide Public, Timely, and Consistent Payment Determinations**

AdvaMed recommends that CMS require Medicare Administrative Contractors (MACs) to publish certain information related to payment determinations online and in a clear, timely, and consistent manner. Presently, the ESRD PPS Final Rule provides discretion to the MACs to establish TPNIES payment rates based upon invoices received, but it lacks instruction as to how or when to apply. Providers and facilities will likely avoid adopting new and innovative equipment and supplies in order to minimize their financial risk, and a pattern of avoidance will impose barriers to patient access to such new and innovative technologies. In order to resolve these ambiguities and increase patient access, we recommend that CMS instruct the MACs to publish an online database that provides 1) a discrete TPNIES payment amount, 2) using invoices submitted as a price floor for each eligible product, 3) no later than March 31 of the first year of TPNIES eligibility, and 4) that will remain effective for the entire TPNIES period.

### **Articulate a Process for Appealing Adverse Determinations**

Finally, AdvaMed recommends that CMS establish a formal appeals process for manufacturers whose applications for TPNIES were denied. We are concerned that without an opportunity to review CMS's initial determination, situations may arise in which new technologies failed to

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obtain a favorable TPINES determination due to technical errors or insufficient information necessary in the initial TPNIES application. A formal appeals process would ensure that applicants to the TPNIES application process would have an opportunity to seek additional, independent review as necessary. The standard process for seeking review of Medicare Part A/B claims may not apply here.<sup>2</sup> However, we are mindful that CMS has in the past set forth a framework for conducting administrative appeals within the Office of Medicare Hearings and Appeals (i.e., a hearing before the Departmental Appeals Board). We believe CMS has the authority and we encourage CMS to apply the same reasoning here.

We greatly appreciate your leadership in changing the status quo of kidney care and would be happy to further discuss these recommendations and the positive impact they could have on ESRD patients' lives. We would be pleased to answer any questions regarding these comments. Please contact me or Chien-Wei Lan at [clan@advamed.org](mailto:clan@advamed.org), if we can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "Donald May". The signature is written in a cursive, flowing style.

Donald May  
Executive Vice President  
Payment and Health Care Delivery

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<sup>2</sup> See generally 42 C.F.R Part 405, Subpart I.