Application for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End-Stage Renal Disease Prospective Payment System for Calendar Year (CY) 2023

To implement the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) effective January 1, 2020 and provide an opportunity for interested parties to apply for the TPNIES for new and innovative renal dialysis equipment and supplies beginning January 1, 2023, CMS is providing the following technical instructions.

DEADLINE

Submit a complete application with a response to each question listed below in the Required Information section no later than February 1, 2022. An application is considered complete when all of the information requested has been submitted by the date specified.

WHERE TO SEND APPLICATIONS

Submit an electronic version of the application via email to ESRDApplications@cms.hhs.gov. Emailed versions of the materials must be compatible with standard CMS software such as Adobe Acrobat DC for 2015 or Microsoft Word 2010. The subject line of the email must say ESRD PPS TPNIES application. Total attachments in one email must not exceed 20 megabytes. If necessary, send multiple emails with attachments less than 20 megabytes. Questions pertaining to the TPNIES process may also be sent to the electronic mailbox noted above.

Please note: In order to meet the February 1, 2022 deadline, an applicant must submit the electronic version of the application via email prior to or on February 1, 2022.

REQUIRED INFORMATION

Applications must include a response to each question below. CMS may request other information to evaluate specific requests for the TPNIES. A separate application is required for each distinct equipment or supply included in the TPNIES request.

1. Name, address, telephone number, and email address for the primary and backup contact for the application. If using a consultant, provide a contact from the manufacturer in addition to the consultant's contact information.

2. Trade/brand name of the equipment or supply.

3. Describe the technology in general terminology. What is it? What does it do? How is it used? Also, submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles relevant to the new equipment or supply.

4. Have you submitted an application for pass-through payments under the Medicare outpatient prospective payment system or new technology add-on payments under the Medicare inpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval.

5. Under what pathway are you seeking marketing authorization from FDA? What is the date of anticipated FDA marketing authorization for the equipment or supply? Provide a copy of the FDA marketing authorization. If marketing authorization has not yet been granted, provide a copy of the authorization to CMS immediately after it becomes available. Per 42 CFR § 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by the HCPCS Level II Code Application Deadline for Biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

6. List the name and telephone number or email address of a contact at FDA who is knowledgeable about the submission for marketing authorization for the new equipment or supply listed above.

7. Will the equipment or supply be available on the market immediately after FDA marketing authorization? If not, provide the date that the equipment or supply came on the market (that is, first sales or availability) and an explanation and documentation of any anticipated delay (for example, manufacturing issues or other reasons). If commercial availability has not yet occurred, provide proof of commercial availability to CMS immediately after it becomes available, for example, a manufacturer's bill of sale. Note that the manufacturer must inform CMS by September 1, 2022 if the equipment or supply will not be available by January 1, 2023.

8. Is there an investigational device exemption (IDE) number from the FDA assigned to the equipment or supply? If yes, please provide this code. Refer to FDA's Frequently Asked Questions about IDE webpage for more details.

9. What class (I, II, or III) was/is assigned to the equipment or supply? Refer to FDA's Overview of Device Regulation webpage for more details.

10. Has an application for an HCPCS code been submitted? If not, please note that submission of the HCPCS application is required by the HCPCS Level II Code Application Deadline for Biannual Coding Cycle 2 for DMEPOS items and services (as specified in the HCPCS Level II coding guidance on the CMS website).

11. What is the anticipated cost of the equipment or supply to the ESRD facility, per treatment? Provide a breakdown of how the cost of the new equipment or supply is calculated.

12. What is the anticipated Medicare and non-Medicare volume of this equipment or supply for the 2 years in the TPNIES period? Describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your equipment or supply, not the total population eligible for the equipment or supply.

13. As required by 42 CFR § 413.236(b)(5), using the information described in the TPNIES Substantial Clinical Improvement Criterion, identify and describe how the new and innovative renal dialysis equipment or supply meets the criteria for substantial clinical improvement over existing renal dialysis services. Provide an annotated list and copies of published peer-reviewed articles relevant to the new and innovative renal dialysis equipment or supply. In the annotation,

please clearly summarize each article, describe the purpose of the article, and the relevance to the equipment or supply.

Note: Applicants are not required to submit proprietary or confidential information as part of the application. However, an applicant may choose to include such information to support its request. Applicants should be aware that information they include in an application is not explicitly protected from disclosure in response to a Freedom of Information Act (FOIA) request. However, FOIA does include an exemption for trade secrets and commercial and financial information obtained from a person that is privileged or confidential. Applicants should indicate what information in the application they consider to be trade secret or commercial and financial information.

Although applicants may mark information in this application as confidential and proprietary, the information may be subject to disclosure under FOIA unless, consistent with FOIA exemption (b)(4), the information relates to trade secrets and commercial or financial information that is exempt from disclosure. Applicants that mark information as confidential and proprietary must substantiate the confidentiality of this information by expressly claiming substantial competitive harm if the information is disclosed, and demonstrate in a separate statement how the release would cause substantial competitive harm pursuant to the process in Executive Order 12600 for evaluation by CMS. CMS cannot guarantee this information will not be subject to release under FOIA.