American Nephrology Nurses Association (ANNA) Calendar Year 2021 Medicare ESRD Final Rule	
ANNA Comments	**Final Rule**
PPS Base Rate ANNA appreciates and supports the Agency's proposed $255.59 or 2.2 percent increase for the ESRD PPS base rate for CY 2021.	The ESRD PPS base rate for CY 2021 is $253.13. The addition to the base rate of $9.93 to include calcimimetics, and a productivity-adjusted market basket increase as required by statute.
Acute Kidney Injury (AKI) Payment Rate ANNA supports the proposed CY 2021 AKI payment rate of $255.59 for AKI, which is the same as the base rate proposed under the ESRD PPS for CY 2021.	CMS updates the AKI payment rate for CY 2021 as $253.13, which is the same as the base rate finalized under the ESRD PPS for CY 2021.
TPNIES ANNA strongly supports the advancement of technology and innovation in the treatment of kidney disease, but we believe the structure of the Medicare ESRD payment system does not encourage the development of new treatment options. We support the Transitional Drug Add-on Payment Adjustment (TDAPA) and the Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES) to address this issue.	CMS expands eligibility for the TPNIES to include certain capital-related assets that are home dialysis machines when used in the home for a single patient.
Ultrafiltration Rate ANNA supports CMS's proposals to modify the Ultrafiltration Rate and Medication Reconciliation reporting measures to a "patient-months" model, to improve alignment with the National Quality Forum (NQF) endorsed measures.	CMS finalizes the proposal to update the Ultrafiltration Rate reporting measure so that facilities are scored based on the number of eligible patient-months, instead of facility-months.
NHSN Validation Study ANNA supports the CMS proposal to reduce the submission requirement for facilities selected to participate in the NHSN validation study from 40 to 20 patient records from any two quarters during the applicable calendar year.	CMS finalizes the proposal to reduce the patient records required for the NHSN validation study. The final policy will review 20 charts per facility across a specified validation timeline and that are acquired by randomly selecting approximately 300 facilities would continue to meet the medical record selection criteria outlined in the NHSN Dialysis Validation methodology.

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NHSN Bloodstream Infection ANNA continues to join with others in the kidney community in requesting that the Agency eliminate the NHSN Blood Stream Infection measure and use of the Dialysis Event Reporting Measure alone. We support transparency and efforts to reduce bloodstream infections, but we concur with KCP's statement that a measure inadequately representing a facility's performance limits the ability of patients to make informed decisions regarding their care. In addition, the use of these measures penalizes facilities pursuing and reporting hospital infection data needed to provide a complete picture of infection rates.	The rule clarifies the timeline for facilities to make changes to their NHSN Bloodstream Infection clinical measure and NHSN Dialysis Event reporting measure data.
Calcimimetics ANNA appreciates that CMS used a three-year transitional add-on period before adding calcimimetics to the ESRD PPS bundle. As mentioned in the ANNA 2019 comment letter and detailed in KCP's 2020 comment letter, this transitional period allowed accumulation of accurate claims data for these products. We agree with KCP's recommendation that the Agency use the most recent publicly available data in establishing the utilization rate for calcimimetics. As explained by KCP, using the most recent 12 months of data aligns with the Agency's proposed use of the most recent Annual Sale Price data in establishing the price for calcimimetics, and would be consistent with the approach used in other Medicare payment systems.	CMS to use 12 full months of data for determining utilization. The preamble implies that CMS is also concerned that utilization may change once the products are bundled, which could lead to an overestimate of the cost of the products and result in the need to rebase.

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TDAPA We support the Transitional Drug Add-on Payment Adjustment (TDAPA) and the Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES)... However, we continue to share the concerns of KCP and other organizations about the long-term stability of the ESRD payment system, because the current policies do not sufficiently adjust the base payment rate when the agency adds new products to the bundle.	"Currently, the TDAPA payment is applicable for a minimum period of 2 years. For new drugs and biological products that are eligible for the TDAPA in the future and are not considered included in the ESRD PPS base rate. CMS will continue to require that the TDAPA is paid until sufficient claims data for rate setting analysis is available, as required by the regulations. When a new renal dialysis drug or biological product is already included in a functional category, then the purpose of the TDAPA is to facilitate uptake of the new product into the business process of the ESRD facility."
Low Volume Payment Adjustment ANNA is encouraged by the increased flexibility provided by the Agency in the application of the low-volume payment adjustment (LVPA). ANNA supports KCP's recommendation of a single low-volume facility adjuster that would better target payments for facilities providing fewer than 4,000 treatments per year. The revised adjuster would resolve the issues created by the overlap between the LVPA and rural adjusters, by replacing them with the single low-volume facility adjuster recommended by KCP.	CMS finalizes the proposal to hold harmless ESRD facilities that would otherwise qualify for the LVPA but for a temporary increase in dialysis treatments furnished in 2020 due to the Public Health Emergency. CMS indicates that it will consider the recommendations to modify the LVPA and rural adjuster to create a single tiered adjustment in future rulemaking.
Standardized Transfusion Ratio ANNA supports the Agency's decision to convert the Standardized Transfusion Ratio (STrR) to a reporting measure. We continue to recommend that CMS replace the STrR with a low hemoglobin (Hgb) measure.	Beginning in Payment Year 2022, CMS will convert the STrR clinical measure to a reporting measure.