



August 24, 2018

The Honorable Alex M. Azar II
Secretary, Department of Health and Human Services
Attention: CMS-1720-NC
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C 20201

RE: CMS-1720-NC; Medicare Program; Request for Information Regarding the Physician Self-Referral Law

Dear Mr. Secretary,

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. We are writing with regard to the CMS request for information (RFI) on how to address any undue regulatory impact and burden of the physician self-referral law, also known as the “Stark Law.”

RPA’s comments will first discuss in general the utility of the physician self-referral law in the evolving era of alternate payment models (APMs). This evolution is characterized by a shift in emphasis from the previous volume-based, fee-for-service models to value-based models across the Medicare payment universe. Specific to nephrology, our comments will focus on three areas where the specialty would benefit from greater clarity: inpatient hospital services similar to dialysis services, dialysis care provided in the outpatient hospital setting, and ancillary services provided concomitant to those services accounted for in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) bundle of care.

Self-Referral Laws in the Era of Coordinated Care and Alternate Payment Models

RPA recognizes that in previous decades the self-referral laws served as a useful guardrail in the effort on the part of then-HCFA and now CMS to fulfill its fiduciary responsibilities in administering the Medicare program. However, given that in the context of emerging APMs greater numbers of physicians are accepting financial risk in these models to an unprecedented level, we believe that time is past, and as such we commend CMS for seeking ways to mitigate the barriers resulting from physician self-referral laws.

Self-Referral Barriers Specific to Nephrology Services

Since the advent of self-referral laws and the accompanying development of the list of Designated Health Services (DHS), dialysis has been specifically excluded from the list of DHS and thus does not implicate the self-referral laws. However, there are at times overlap between some aspects of dialysis and related services and DHS that RPA believes would benefit from greater clarity in the relevant regulation, and which are outlined below.

The first pertains to the apheresis family of services (apheresis, plasmapheresis, etc.) when provided in the inpatient hospital setting. Dialysis services and apheresis services are similar in nature in that they both involve filtration of blood, are often provided infrequently and on an emergency basis in the hospital setting and utilize similar equipment. Inpatient dialysis is specifically excluded from the definition of inpatient hospital services which are DHS. However, apheresis services are not. **As such, RPA urges CMS to specify that the family of CPT codes for apheresis (Codes 36511-36522) be specifically noted as excluded from the list of DHS.**

Secondly, RPA urges CMS to explicitly add outpatient dialysis provided in hospital settings to the list of exclusions from DHS as they pertain to outpatient hospital services. As noted above, this is owing to what we believe is an absence of clarity regarding their status as it pertains to DHS. While inpatient and outpatient hospital services are included on the DHS list, inpatient dialysis has always been explicitly excluded; **outpatient dialysis (provided in settings such as observation or 23-hour care centers) is not explicitly excluded, and we urge CMS to do so.**

The third gray area affecting kidney disease care regards ancillary services that are not renal related but occur in conjunction with the dialysis care provided in outpatient dialysis facilities, which is reimbursed through the ESRD PPS. The ESRD PPS bundle is quite specific as to which services are included and excluded, but there are a range of services that are provided in outpatient dialysis facilities on occasion in the typical course of care for ESRD patients that are not part of the PPS, such as drugs and laboratory tests (e.g., drugs such as certain intravenous antibiotics and laboratory tests such for thyroid stimulating hormones or Hgb A1C for diabetes). **These ancillary services that are separate and distinct from those included in the ESRD PPS are currently not explicitly specified as being excluded from the DHS list. As with the previous examples, we urge CMS to provide further clarity in this area and make this presumed exclusion explicit.**

As always, RPA welcomes the opportunity to work collaboratively with HHS/CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to HHS/CMS in its future work to reduce unnecessary and inappropriate regulatory burdens affecting Medicare providers. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael D. Shapiro". The signature is fluid and cursive, with the first name "Michael" being more legible than the last name "Shapiro".

Michael D. Shapiro, MD, MBA, FACP, CPE

RPA President