

Second phase of interim final regulations to Stark law clarifies issues for dialysis providers

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ON MARCH 26, THE CENTERS FOR MEDICARE & Medicaid Services (CMS) released Phase II of the regulations implementing Stark II, the federal physician self-referral law. This law provides that a physician may not make a referral to an entity in which the physician or the physician's immediate family has a financial relationship for a designated health service (DHS) unless the arrangement is covered by a statutory or regulatory exception. A number of points in the Phase II regulations directly impact dialysis providers. The Phase II regulations become effective July 26; the comment period runs through June 24, 2004.

Fair Market Value

Certainly one of the more significant topics covered in the Phase II regulations is the establishment by CMS of a "safe harbor" provision under the fair market value definition for hourly payments to physicians for their personal services. In response to a comment recommending the establishment of benchmarks for evaluating the fair market value of dialysis center medical director compensation, CMS declined to set a fixed, industry-wide fair market rate for medical directors of dialysis facilities. CMS, however, has provided in the Phase II regulations two methodologies for calculating fair market hourly rates for compensating medical directors.

Under the first methodology, the hourly rate must be less than or equal to the average hourly rate for emergency room physician services in the relevant physician market. There must be at least three hospitals providing emergency room services in the relevant physician market to use this first methodology. CMS does not provide guidance on determining the relevant physician market.

Under the second methodology, the hourly rate is calculated by determining the average among at least four national compensation surveys of the 50th percentile national compensation level for physicians in the same physician specialty and dividing the average by 2,000 hours. Six national compensation surveys are listed in the Phase II regulations.

Although compliance with these methodologies is voluntary, CMS makes clear in the preamble to the Phase II regulations that DHS entities using either of the compensation methodologies will be assured that their compensation rates will be deemed fair market value. The example given in the preamble should be of great interest to dialysis providers. "We believe that nephrology salary data from four surveys could be used to calculate an hourly payment for medical directors of end-stage renal disease (ESRD) facilities" (see page 16,092 of the *Federal Register*, Vol. 69, No. 59). CMS notes that providers using compensation methodologies to determine fair market value other than the two offered by CMS in the Phase II regulations will continue to bear the risk that their compensation rates may not be fair market value. Therefore, companies choosing alternative methodologies to determine fair market value compensation are at greater risk once the Phase II regulations go into effect.

EPO and Other Dialysis-Related Drugs

The first phase of the Stark II regulations had provided an exception from the outpatient prescription drug referral prohibition for erythropoietin (EPO) and other dialysis-related drugs identified in the regulations by current procedural terminology and healthcare common procedure coding system codes. The new Phase II regulations expand the list of drugs which are excepted. More important, the list of drugs is expanded to include Aranesp, albumin and levocarnitine, an additional Vitamin D drug, and three additional thrombolytics. CMS warns that they will monitor use of this exception and may revisit the exception if abuse is determined.

Medical Director Agreements

Commentators to the Phase II regulations argued that medical director contracts and other employment or services contracts entered into in connection with the sale of a dialysis facility to a corporate owner should be treated as part of the sales price and considered when determining the sale's fair market value. In the preamble to the Phase II regulations, CMS rejects that argument, indicating that the sale of the dialysis facility and the employment contracts (which presumably include medical director agreements) are separate arrangements. Each requires its own fair market value compensation.

Corporate-Owned Laboratories

In response to commenters owning independent dialysis laboratories, CMS concluded that the Stark law does not cover referrals between a company-owned dialysis facility and the company-owned laboratory if there is no referring physician involvement. CMS further noted that there may be indirect compensation arrangements between a medical director and the corporate-owned laboratory that would need to fit within the indirect compensation exception. Physician compensation, which takes into account laboratory referrals, would not fit within the exception and is illegal under Stark II.

Conclusion

The Phase II regulations clarify key points important to providers of dialysis services, especially with guidance on determining fair market value for medical director compensation. Greater guidance, though, creates more risk for providers who continue to follow the "business as usual" approach and ignore this newly provided guidance. Dialysis providers would be well served to review their arrangements in light of the new Phase II regulations and to develop a strategy to deal with this ever-changing regulatory environment.

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