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Some Helpful Managed Care Guidance Provided in Advisory Opinion 18-11

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Practitioners in the Medicare or Medicaid managed care space place heavy reliance on the protection of the Anti-Kickback Statute (AKS) Safe Harbor found at 42 C.F.R. § 1001.952(t), generally known as the "EMCO [eligible managed care organization] Safe Harbor," as they look at incentive arrangements between providers and managed care plans. Although the language of the regulation is generally understood, there has not been any guidance from HHS's Office of the Inspector General (OIG) since the publication of the final rule containing the safe harbor.

The case law has also not offered guidance with respect to the application of the Safe Harbor, but has indicated that the AKS clearly can be implicated by managed care arrangements. See United States ex rel. Wilkins v. United Health Group, 659 F.3d 295 (3d Cir. 2011) (A plan's offer of payment to a physician group to move its patients from a competing plan to it can implicate the AKS and the False Claims Act.)

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On October 18, 2018, in Advisory Opinion 18-11, the OIG has now offered some guidance to the application of the EMCO Safe Harbor. At issue, was a proposal by a Medicaid Managed Care plan to pay an increased amount of compensation to providers that meet benchmarks for increasing the amount of Early and Periodic Screening Diagnostic and Treatment (EPSDT) services to Medicaid recipients from birth to age 21. Under the proposed compensation plan with providers, there were three different compensation levels, based on an increasing amount of EPSDT services being provided. That is, if a provider increased the services to existing enrollees by 10% over the base year, there would be an incentive payment of $1.00 per existing enrollee who received the services, if the percentage increase was 20%, there would be a $2.00 incentive payment, and if the percentage increase of 30% or greater, there would be a $3.00 incentive payment. Thus the payments would increase as more services were provided.

The arrangement would be set forth in a written agreement, signed by the parties, specifying the items or services covered and specifying that the provider could not claim payment in any form from a federal health care program for the items or services. The opinion requestor also stated that the proposed arrangement would not provide an incentive to recruit new Medicaid recipients, because the incentive payments would be based only on the percentage change in volume of the EPSDT services to existing enrollees from one year to the next. In addition, the requestor represented that there would not be any inducements to participate in other lines of business as part of the arrangement. Finally, the requestor certified that the purpose of the arrangement was not to increase its capitated payment rates in the future; nor did it assess the potential for increased capitation payments as a result of the increase in costs as a result of the arrangement.

In reviewing the proposed arrangement under the terms of the EMCO Safe Harbor, the OIG noted at the outset that the safe harbor excludes from the definition of "remuneration" for purposes of the AKS any payments between EMCOs and first tier contractors for providing or arranging for items or services covered by the plan, if the specific requirements of the safe harbor are met. What was unusual about this particular arrangement, was that the plan proposed to pay the providers to increase the volume of services provided.

Because the plan, in this case, was a Medicaid managed care plan that was capitated by the relevant State, the

initial criterion that the plan be an eligible managed care organization was met. Similarly, because the providers were contracting directly with the plan, they clearly were first tier contractors. In addition, because the payments would be for increases in services provided by the plan to the Medicaid recipients, the incentive payments met the health care items or services definition. In reaching the conclusion that the proposed payment structure was included under the safe harbor, the OIG made it clear that the safe harbor protects "any payments" made, and the term "payments" is not further defined. Thus, it does not matter "whether payments…are price reductions …or payments…to accomplish certain care delivery goals under a capitated risk contract." (Opinion, p. 7, fn. 6). In other words, the "method of payment" is not material, as the total federal payment exposure is fixed in accordance with the contract with the managed care organization.

With respect to the Safe Harbor's requirement that "[n]either party shifts the financial burden of the agreement to the extent that increased payments are claimed from a federal health care program," 42 C.F.R. § 1001.952(t)(1)(ii)(C), the OIG considered the possibility that the capitated payments made by the State to the Medicaid managed care plans could increase due to the increase of services under the arrangement, and delved into the intent of the requestor plan. The OIG believed that the potential increase was consistent with the State's goal of ensuring appropriate services for this population, which services might allow detection and care to avert health problems as early as possible. This, coupled with the representation by the requestor that the purpose of the arrangement was not to increase rates in future years, was sufficient for the OIG to conclude the intent was not improper and did not suggest a violation of the AKS. It also seems likely that even without the requestor's certification, the result would not have been different and the case could be made that by increasing the costs incurred through this arrangement, over time there would actually be a net savings. However, the OIG's analysis seems suspect. The safe harbor's requirement relates to the shifting of the financial burden under the agreement, whereas the capitated payment rates at issue here are set by the State and are outside the agreement between the requestor plan and the providers, and not within the control of the parties to the agreement. Moreover, the OIG's consideration of the intent of the requestor seems odd, because the safe harbors are meant to protect arrangements that are structured in such a way as to be sufficiently innocuous so as to be outside the reach of the AKS regardless of intent. The purpose of the safe harbors is to provide parties bright line assurance that an arrangement will not be subject to prosecution under the AKS (or sanction under the Civil Monetary Penalty Statute) if it meets the requirements of a safe harbor.

Finally, the remaining elements of the EMCO Safe Harbor were easily met – the arrangement was reduced to writing, the term was for at least a year, and was not a part of a swapping arrangement.

In conclusion, the OIG has helpfully confirmed that the EMCO Safe Harbor does indeed protect "any payment," but it has injected a measure of uncertainty as to what is meaning of the requirement that costs not be shifted, and whether and to what extent intent of the parties is relevant. That may have been because of the framing of the question by the requestor, or for some other reason. We hope, however, that it was superfluous to the conclusion, as to conclude otherwise would seem inconsistent with the goals of the Safe Harbors.