Health Law Update

by Robert J. Baror

Transportation and the Anti-Kickback Statute: A Tortured Route with a New Safe Harbor

Health-law attorneys are well aware of the quagmire that can result when health-care providers attempt to engage in even the simplest forms of patient outreach, such as when hospitals provide shuttles to pick up patients and bring them to appointments. Seemingly innocent attempts to facilitate medical care can easily look like criminal schemes to give kickbacks to patients to induce them to see medical providers, when viewed through the eyes of the Department of Health and Human Services Office of the Inspector General (OIG). However, the OIG is offering some new relief to health-care providers in the form of the proposed safe harbor for the provision of local transportation services spelled out in the proposed rule released on Oct. 3: 79 Fed. Reg. 5917 (Oct. 3, 2014). Yet, this proposed rule is not a blanket invitation for providers to begin offering wide-ranging transportation services to patients, because even under the proposed rule, many caveats and concerns are raised. Therefore, close scrutiny of the proposed rule, comments to be submitted, and the nuances of the final rule to be produced is necessary.

To understand how a hospital's attempt to send a van to pick up a cancer patient for chemotherapy can morph into a criminal conspiracy, one has to understand the anti-kickback statute. The statute incorporates the premise that because, generally, the more patients a medical provider sees, the more revenue the provider generates from federal health-care programs, like Medicare, then anything "given" to patients that makes them more likely to see the medical provider may be a prohibited kickback that could lead to criminal prosecution or civil monetary penalties. This kickback would potentially have the result of generating more fees for the medical provider, while concomitantly driving up the cost of federal health-care programs. Accordingly, while all arrangements that provide some benefit to patients are not per se banned under the anti-kickback statute, because intent is an element for a statutory violation, providers must be wary of placing themselves in a situation that might look like an anti-kickback statute violation, lest they be forced to spend large sums litigating the issue of intent. It is important to note that even if there are benign purposes to a transportation program, if even one purpose is to induce referrals, this is enough to establish intent (*United States v. Kats*, 871 F.2d 105 [9th Cir. 1989]). Thankfully, there is some regulatory relief for health-care providers seeking to assist their patients without running afoul of the anti-kickback statute: As long as an arrangement fits within a regulatory safe harbor, then it is exempted from the anti-kickback statute's prohibitions.

Transportation provided to patients, which is seemingly innocuous, has long enjoyed some protection from anti-kickback statute enforcement. The act's legislative history itself indicates that Congress did not intend to "preclude the provision of complimentary local transportation of nominal value" (79 Fed. Reg., at 59721, citing to H.R. Conf. Rep. No. 104-736, at 255 [1996]). Accordingly, the OIG has interpreted the anti-kickback statute as not prohibiting transportation services of nominal value—no more than $10 per item or $50 in the aggregate course of a year (65 Fed. Reg. 24400, 24408, 24411 [April 26, 2000]). However, this general guidance left great latitude for OIG enforcement against transportation programs.

Because many patients in need of medical care have transportation difficulties due to age, disability, or financial hardship, health-care providers have continually sought means to provide transportation services to these patients without violating the anti-kickback statute. With the lurking threat of anti-kickback statute prosecution, health-care providers turned to the OIG for advisory opinions seeking to have their transportation programs blessed. (*See* OIG Advisory Opinion No. 00-7; OIG Advisory Opinion No. 11-12.) The OIG has, in fact, provided advisory opinions allowing certain transportation programs to go forward. However, the drawback of an advisory opinion is that it is only applicable to the requestor, and while it is a source of guidance, it is not binding upon the OIG in future cases. Therefore, an advisory opinion is not a definitive yardstick against which other proposed transportation programs can be judged.

Thus, the newly proposed transportation safe harbor for free or discounted transportation is a welcome development, because it will provide health-care providers with more certainty about allowable arrangements. But the proposal still contains many limitations of

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which providers need to be aware. One significant limitation is that, if adopted, the safe harbor would only cover transportation services provided to existing patients. Therefore, new or prospective patients would have to be screened out of any transportation program. The purpose of this restriction is so that health-care providers cannot use the promise of transportation as a lure for new patients and to increase business. As the OIG appears to see it, easing transportation difficulties for existing patients provides a benefit without the potential for incentivizing overuse that exists when new patients are given the promise of the benefit of free transportation.

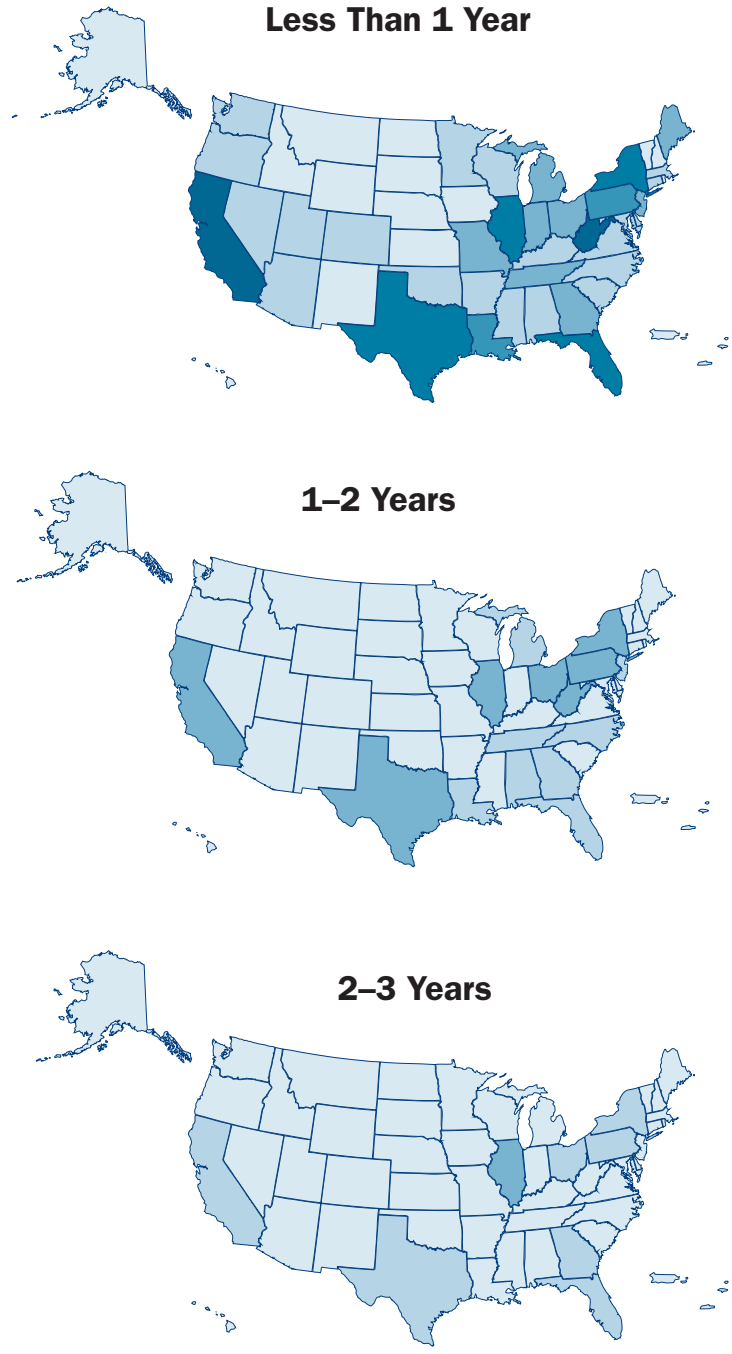
The proposed transportation safe harbor also specifically excludes certain entities or individuals. One class of excluded entities is suppliers of durable medical equipment or pharmaceutical companies. The OIG has crafted this exclusion because it believes "that there may be additional risk that these types of entities, which are heavily dependent upon practitioner prescriptions and referrals, would use transportation arrangements to generate business for themselves by steering transported patients to those who order their products. Moreover, these suppliers and manufacturers do not have the broader patient care responsibilities that, for example, hospitals, health systems, clinics, and physicians have" (79 Fed Reg., at 59722). The OIG, voicing similar concerns about laboratories, has also excluded them from the proposed transportation safe harbor. Additionally, the OIG is concerned about the possibility of overutilization if home health-care providers offer transportation to physicians' offices, and it is therefore considering excluding home health-care providers from the safe harbor when they furnish transportation to referral sources but not when they provide transportation to nonreferral sources, such as pharmacies.

The OIG is also proposing additional safeguards to the newly proposed transportation safe harbor. Among these are the exclusion of transportation programs made available only to patients who were referred by particular health-care providers or suppliers. Moreover, transportation could not be contingent on a patient's seeing specific providers or suppliers who may be referral sources. Though generally the OIG would prohibit health-care providers from restricting transportation to patients based upon the type of treatment they receive, for fear that transportation would be limited to patients receiving more profitable treatments, one restriction on transportation users that would be allowed is the limitation of a transportation program to patients whose conditions require frequent or critical appointments and who lack reliable transportation.

The OIG, while seeking to allow some latitude in transportation arrangements, still remains concerned about the potential for these arrangements to generate overutilization. Therefore, the proposed safe harbor would exclude transportation services that are publicly advertised or marketed to patients or others who are potential referral sources. Additionally, drivers could not be compensated per patient who received transportation. They would have to be compensated in some manner that did not take into account the number of patients picked up, such as by mileage or through an hourly wage. Moreover, safe harbor protection would not apply if health-care items or

JUDICIAL HEAT MAP

*U.S. District Courts—Civil Cases Pending as of Sept. 30, 2013**



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services were marketed to patients during the course of their ride—though signage on the vehicle indicating the health-care provider offering the transportation would be allowed.

The proposed new safe harbor is targeted only at local transportation. Air travel is specifically excluded from the safe harbor, and the proposed rule would limit travel distance to 25 miles. However, the OIG recognized that the hard-and-fast 25-mile proposal could be problematic in rural areas, health professional shortage areas, and medically underserved areas. Therefore, the OIG has solicited comments on how it should define "local transportation," including whether it should permit free or discounted transportation to "the nearest facility capable of providing medically necessary items and services, even if the beneficiary resides farther away than the proposed mileage limits would otherwise allow" (79 Fed. Reg. 59724).

Another issue on which the OIG has solicited comments is whether the proposed safe harbor should be modified to account for integrated networks of providers and suppliers. The OIG has sought comments on whether it is appropriate for an entity to furnish an existing patient with transportation to a new provider of which he or she is not a patient. The OIG is also looking at whether health-care providers should be allowed to provide transportation only for medical purposes or if they should be allowed to provide free or discounted transportation for other purposes that relate to the patient's health care, such as to apply for government benefits, obtain counseling, or get to food banks or food stores.

In terms of what record keeping and data collection would be necessary in order to insulate a health-care provider from accusations that it has strayed outside of the safe harbor, the OIG is seeking comments on what "documented beneficiary eligibility criteria" should exist (79 Fed Reg., at 59723). Obviously, the degree of onerousness that the OIG adopts in terms of documentation will have a significant impact upon the cost to operate transportation programs and the attractiveness of these programs to health-care providers.

While the OIG's concern about the possibility of transportation programs generating overutilization may seem excessive, it is not completely unfounded. For example, in 2009 five New York hospitals were accused by then-State Attorney General Andrew Cuomo of violating New York State's anti-kickback statute by paying a contractor, SpecialCare Hospital Management Corp., to literally round up homeless individuals and transport them to detox units at the hospitals for treatment ("Seven Hospitals in N.Y. Accused of $50M Medicaid Fraud," USA Today, Jan. 5, 2009, usatoday30.usatoday.com/news/health/2009-01-05-medicaid-lawsuits_N.htm, last accessed Dec. 7, 2014). However, this appears to be the great exception, rather than the rule, when it comes to health-care provider transportation programs—the vast majority of which appear beneficial to society and many of which have already been blessed by the OIG through advisory opinions.

The proposed new transportation safe harbor seeks to codify much of what the OIG has stated previously in its advisory opinions. However, it will provide the health-care community with the benefit of more certainty when it comes to the acceptable design of transportation programs—though differing interpretations of the rule will still prohibit complete certainty. The final version of the rule remains to be seen, and one should keep an eye out for developments that particularly relate to integrated providers and suppliers, such as accountable care organizations. Additionally, the comments generated in response to the OIG's solicitations will be particularly interesting and may influence the shape of the safe harbor when it ultimately takes effect. In the final analysis, the OIG is providing structure to the general thrust of its enforcement, which it has already outlined previously, but much remains in flux, and thus health-care providers should still have their counsel closely scrutinize any new transportation programs to be implemented to make sure that they steer clear of any minefields existing within the safe harbor. ⊙