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New Safe Harbors and Inducement Protections

This newsletter is not legal advice, it is informational only. Any reader should consult an attorney for legal advice.

As a slightly early Christmas gift, the Office of the Inspector General in December, 2016, published new safe harbors under the Anti-kickback statute along with protection for certain behaviors under the civil money penalties rules. Some of the safe harbors protect pharmacies, certain emergency ambulance services, remuneration between Medicare Advantage organizations and federally qualified health centers as well as drug manufacturers. However, of significance to physicians will be the protection for free or discounted local transportation services that meet specified criteria. Similarly, under the civil money penalty authorities, new protections were published both for remuneration that poses a low risk of harm and promotes access to care, as well as certain remuneration to financially needy individuals. As with most publications of this type from the OIG, there are a host of interpretations to be applied to these new protections.

Local Transportation

The new safe harbor protects transportation both to a provider or supplier of services and back to a patient's home as long as all of the conditions of the safe harbor are met. An eligible entity offering free or discounted local transportation need not require that transportation be planned in advance. A transportation program can use vouchers rather than having the transportation provided directly by the eligible entity. Under no circumstances is protection available for air, luxury or ambulance level service.

To qualify for the safe harbor, cost shifting to a federal program for the provided transportation is prohibited. In addition, the transportation may not be advertised. The protection is only available for established patients when individualized services are going to be provided. However, once the patient has called to make an appointment with the physician office or other supplier, they are considered to be "established". Shuttle services, which are not quite as restrictive, are addressed in a separate safe harbor. The local transportation safe harbor protects transportation for patients to obtain medically necessary services. While there is no requirement to document that the patients receiving the benefit are established patients, maintaining such documentation, the OIG says, may be best practice.

Eligible entities that want to provide such transportation must have a set policy regarding the availability of transportation assistance and must apply that policy uniformly and consistently. Again, although documentation is not required, it is deemed to be best practice to demonstrate compliance with requirements of the policy. Examples of variable criteria that might be utilized include

a policy where transport is provided to any patient whose ability to drive himself or herself home after a procedure is at issue. Another practice, they observe, might offer local transportation assistance to any patient who has a history of missing appointments. If an eligible entity establishes a needs based policy, they must be able to demonstrate how they applied that. The marketing of free or discounted transportation is prohibited. However, the OIG agrees that signage designating the source of transport on vehicles used to transport patients is an important safety feature and would not be considered marketing for purposes of the safe harbor. Informing patients that transportation is available is also not marketing if it is done in a targeted manner. If the transportation is offered by a driver or private company hired by the eligible entity, that eligible entity cannot pay the driver or a person involved in arranging for the transport on a per patient transported basis although it could pan the basis of total distance traveled by a vehicle. If the transportation is provided in the form on non-private transport such as a taxi or bus, the transportation would be paid for or reimbursed to individual patients through vouchers, bus fare or cash reimbursement if the patient has a receipt showing that they incurred the cost.

The safe harbor protects only local transport which is defined in urban areas as 25 miles and in rural areas as 50 miles.

In addition to individualized patient transport, the new safe harbor also protects shuttle transportation. They interpret a shuttle to be "a vehicle that runs on a set route on a set schedule." The established patient requirement does not apply to shuttle services. In addition, they did not mandate where the shuttle can or cannot make stops other than continuing to require that the shuttle transportation be local in accordance with the standards established above. The marketing prohibitions also apply to the shuttle services, except that the shuttle schedule and stops can be posted. The prohibition on other marketing and cost shifting also apply. They do not mandate who runs the shuttle (e.g. the eligible entity or a contractor) and they are not limiting the availability to established patients. In fact, they say "we expect many shuttles would be available to employees of the eligible entity or visitors to one of the eligible entities facilities as well as to patients."

Beneficiary Inducements

Providing exemption from civil money penalties for "other remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs," the OIG takes the position that the burden of defending activities under this exception will fall on those seeking to utilize it.

With regard to promoting access to "care", they take the position that care is items and services that are payable by Medicare or a state healthcare program. The remuneration must increase the beneficiary's ability to obtain care and pose a low risk of harm. As an example, if a patient makes an appointment with a physician practice, the practice may send the patient a monitoring device (such as a blood pressure cuff, heart rate monitor, or purchase code for smart phone app) to collect health data before the appointment. They acknowledge that items or services that support or help patients to access care, or make access to care more convenient than it otherwise would be, often would meet their interpretation.

The form of the remuneration does not matter (as long as it is an item or service, and not cash or a cash equivalent, and not a co-

payment waiver). It could include such things as participation in smoking cessation, nutritional counseling, or disease specific support groups. They offer the example of a primary care group practice that might purchase and make available to its diabetic patients a subscription to a web-based food and activity tracker that includes information about healthy lifestyles. In contrast, they say, an ophthalmologist could not offer a general purpose $20 debit card to every patient who selected him to perform cataract surgery. Under some circumstances a provider could offer free child care so that a patient could attend educational programs. Recognizing that there are socio-economic, educational, geographic, mobility or other barriers that could prevent patients from getting necessary care (including preventive care) or from following through with a treatment plan, their definition of "promote access to care" encompasses giving patients the tools they need to remove those barriers. Dinner or movie tickets would not qualify.

Referring back the 2002 Special Advisory Bulletin which permits inexpensive gifts other than cash or cash equivalents of no more than $10 in value individually or $50 in the aggregate annually per patient, they have raised these limits respectively to $15 for an individual gift and $75 in the annual aggregate.

Remuneration in the form of an item that dispenses medications at a certain time for a patient could qualify as promoting access. Reimbursing parking expenses or providing free child care during appointments also could qualify. In contrast, offering movie tickets whenever the patient attends an appointment would not qualify.

With respect to meeting the standard of "low risk of harm", they are applying three criteria: the remuneration must (1) be unlikely to interfere with or skew clinical decision making; (2) be unlikely to increase cost to federal healthcare programs or beneficiaries through overutilization or an appropriate utilization; (3) not raise patient safety or quality of care concerns. They believe that educational materials do not even require protection, since they are not an item. Lodging before a procedure or transportation to appointments also could be protected under certain circumstances.

Financial Need-Based Exception

Pursuant to a third statutory provision, they have established that remuneration does not include the offer or transfer of items or services for free or less than fair market value, if the items or services are not advertised or tied to the provision of other items or services reimbursed by the Medicare or state healthcare programs; there is a reasonable connection between the items or services in the medical care of the individual; and the recipient has been determined to be in financial need. Acknowledging further that there are some overlaps with the preventive care exception and the exception for remuneration that promotes access to care and poses low risk, the financial need-based exception does not require that the remuneration promote access to care or promote the delivery of preventive care. The items or services offered may not be cash or cash equivalents nor offered as part of any advertisement or solicitation. There is no protection for offers or transfers of items or services that are provider or supplier conditions on the patient's use of other services that would be reimbursed by Medicare or a state healthcare program. The item or service must be reasonably connected to the patient's medical care which they define as the treatment and management of illness or injury and the preservation of health or services offered by the medical, dental,

pharmacy, nursing and allied health professionals. They interpret "reasonably connected to be reasonable from a medical perspective as well as from a financial perspective." A health center, for example, can offer items or services to incentivize preventive care; so that a stroller or school supplies, among other items, could be offered to patients who attended necessary preventive care appointments. On the other hand, a medical professional could not give patients sports equipment (such as a bicycle or a basketball hoop) because the patient needs more exercise. Nor could a provider give tickets to an entertainment event or a gift card for a spa on the grounds that the patient is suffering from anxiety or depression. Items crucial to a patient's safety such as car seats for infants are reasonably connected to medical care. However, not everything beneficial to a patient is connected to medical care. They exclude backpacks when they are not connected to medical care. Just to make parsing these issues even more entertaining, they offer the following example. Giving toys to children typically is not reasonably connected to medical care. However, for some children experiencing developmental delays or recovering from certain illnesses or injuries that require therapy for fine motor skills, "toys" that reinforce treatment or aid in improving a health condition could be reasonably related to that individual patient's medical care. They believe that the medical professional working with the patient is in the best position to determine what is medically reasonable.

With respect to a reasonable connection from a financial perspective, if the incentive is disproportionally large in relation to the value of the applicable service, that would be problematic. Here they offer two contrasting examples. Offering a diabetic patient, compression stockings, could be reasonable from a financial perspective, but paying for a subscription to a long term meal preparation and delivery service for such a patient would not be. On the other hand, providing meal deliveries for a limited period of time after a patient is discharged after a debilitating procedure might be reasonable form both a medical and financial perspective. Disease management programs could qualify.

To qualify for the exception, they expect an individualized assessment of the patient's financial need, in good faith, on a case-by-case basis. They are not requiring any specific documentation although they would expect that entities offering these items would do so in accordance with the set policy that is uniformly applied. Provider or supplier should not rely solely on a representation by a patient that he or she is in financial need, unless the provider or supplier has some independent basis for belief for such a representation is available.

Conclusion

All of these expansions to what providers may do are positive changes. But, as with everything the OIG addresses, there is considerable nuance in applying all of them. We are here to help.