NATIONAL ASSOCIATION OF PSYCHIATRIC HEALTH SYSTEMS
ADVOCATING FOR BEHAVIORAL HEALTH
900 17th Street, NW, Suite 420, Washington, DC 20006-2507 | Ph 202/393-6700 | Fx 202/783-6041 | naphs@naphs.org | www.naphs.org

Submitted via www.regulations.gov

December 2, 2014

Daniel R. Levinson, Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-403-P3
Cohen Building
330 Independence Avenue, SW, Room 5269
Washington, DC 20201

RE: OIG Proposed Rule, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing

Dear Mr. Levinson:

We are pleased to submit comments on behalf of the National Association of Psychiatric Health Systems (NAPHS) with respect to the recently published Office of Inspector General (OIG) Proposed Rule, which would amend existing safe harbors and create new safe harbors to the anti-kickback statute and the civil monetary penalty (CMP) rules.[1] In particular, our comments focus on the OIG's proposal to create a new safe harbor at 42 C.F.R. § 1001.952(bb) that would protect certain free or discounted local transportation services provided to Medicare and Medicaid beneficiaries.

Created in 1933, NAPHS has been a leader in advocating high-quality mental health and substance abuse care delivery for 81 years. NAPHS represents delivery systems working to coordinate a full spectrum of treatment services, including inpatient, residential, partial hospitalization, and outpatient programs as well as prevention and management services. NAPHS advocates for behavioral health and represents provider systems that are committed to

[1] Office of Inspector General (OIG), HHS, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, Proposed Rule, 79 Fed. Reg. 59717, 59717 (Oct. 3, 2014).

the delivery of responsive, accountable, and clinically effective treatment and prevention programs for children, adolescents, adults, and older adults with mental and substance use disorders. Our mission encompasses all organizations serving people with psychiatric and substance use disorders. Our members include integrated health systems, hospitals, units and behavioral health divisions of general hospitals, partial hospitalization programs, community mental health centers, residential treatment centers, youth services organizations, and behavioral group practices located in all regions of the country.

I. General Comments

The ability to provide free or discounted transportation to patients can greatly impact a provider's ability to provide the actual care that a patient requires. We applaud the OIG for taking up the issue of local transportation again and for seeking to create a safe harbor that will allow for free or discounted local transportation to be made available to Medicare and Medicaid beneficiaries, where appropriate. As the OIG considers the language that would frame such a safe harbor, NAPHS urges the OIG to proceed cautiously to ensure that while necessary safeguards are put in place, they are not so restrictive that they inadvertently prevent providers from undertaking legitimate arrangements that are critical to beneficiary health.

Section 1128A(a)(5) of the Social Security Act prohibits

> offer[ing] to or transfer[ring] remuneration to any individual for benefits under [Medicare] or a state health care program that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare], or a State health care program (as so defined).

However, in enacting this section of the statute, Congress did not intend to preclude "the provision of complimentary local transportation of nominal value."[2] The OIG has interpreted "nominal value" to mean no more than $10 per item or service or $50 in the aggregate over the course of a year, but also has acknowledged that this may be overly restrictive in the context of transportation. In 2002, the OIG solicited and received public input on issues related to a possible exception to the statute for complimentary local transportation, but until this recently issued proposed rule, the OIG had not proposed or finalized such an exception.

As the OIG undertakes this effort to create the parameters for such a safe harbor, we urge the OIG to consider the serious need for complimentary transportation from certain specialized populations, especially those with psychiatric and addictive disorders. Patients needing transportation assistance may include, for example, those with a chronic mental illness that impairs their ability to function independently or patients who have been recently released from an inpatient hospitalization and who need outpatient treatment to prevent relapses that would send them into inpatient care again. As a representative of organizations and health systems that provide care to this patient population, we hope that our comments will be helpful as the OIG deliberates upon this issue.

---

[2] 79 Fed. Reg. at 59721 (citing H.R. Conf. Rep. No. 104-736 at 255 (1996)).

In our comments below, we offer our recommendations and input on several key issues that we believe are critical for the OIG to take into account as it considers whether, and if so, how, to create a safe harbor for local transportation. Specifically, our comments address the following issues: (1) Eligibility for transportation: who is an "established patient"; (2) Health systems and networks; (3) Transportation need and/or financial need, and related documentation requirements; (4) Definition of "local" for purposes of eligible transportation; and (5) Advertising for purposes of the safe harbor.

II. Specific Comments

a. Eligibility for Transportation – "Established Patient"

In the Proposed Rule, the OIG solicits comment on whether to limit safe harbor protection to free or discounted local transportation offered to "established patients."[3] The Proposed Rule provides only one example plus one additional sentence to illustrate this point, stating that

> "once a patient has selected an oncology practice and has attended an appointment with a physician in the group, the physician could offer transportation assistance to the patient who might have trouble reliably attending appointments for chemotherapy" and that
>
> "safe harbor protection would not be available to a practice that offers or provides free or discounted transportation to new patients."[4]

We believe that the descriptions of an "established patient" and "new patient" in the Proposed Rule need additional clarification and that, currently, this part of the proposal is too limiting. The example could be read to suggest that the OIG would view *only* a patient who has already "selected" a practice and has "attended an appointment" as an "established patient." Further, while the Proposed Rule does not define a "new patient", the OIG states that protection *will not* be extended for free or discounted transportation from a practice that "offers or provides" free or discounted transportation to "new patients."

In the patient population that our members serve – patients with psychiatric and addictive disorders – many patients would not be capable of transporting themselves to a treatment facility, whether by private or public transportation. For some patients, it is an issue of access and for other patients, their illness impedes their ability to manage or arrange this transportation on their own. In many cases, patients are being discharged to a partial hospitalization program. The importance of the first appointment is critical for this patient population, and studies have shown that if the first appointment is missed, the odds of successfully receiving care in future appointments significantly decrease and the odds of rehospitalization increase. We believe that if the patient has verbally affirmed that they plan to go to a provider for this first appointment, there is an implicit "selection" and establishment of a relationship that has occurred and should allow the person to be eligible for the free or discounted transportation. This scenario, we believe, can be easily distinguished from an abusive scenario where a provider goes out into the

[3] 79 Fed. Reg. at 15722.
[4] Id.

public actively recruiting patients with the lure of free or discounted transportation. As such, we would urge the OIG to recognize the importance of successful transitions among levels of care and to take this into account as it defines the patients who are eligible for free or discounted transportation under the safe harbor.

A further point we would highlight is that some providers have patient rosters that are continuously turning over. A provider may offer a short term, one- or two-month program for a patient and may not see the same patient again for an extended period of time. Some patients may be discharged to a lower level of care, for example, but then may need to come back to the provider at a later date for further treatment. We request clarification that in cases of an "inactive" or "discharged" patient, that if the patient comes back for future care, the safe harbor protection would still apply to them.

In sum, we believe that the term "established patient," if it is used in a safe harbor, must be broad enough to encompass the situations and issues raised above. To withhold free or discounted transportation from patients because they have not yet attended an appointment with a given provider group is far too restrictive, especially in the case of patients with psychiatric and addictive disorders. We believe that any barrier to continuity of care should be minimized and that the OIG should broaden the way in which it interprets an "established patient."

b. Health Systems and Networks

We appreciate that the OIG is considering whether, for health systems and networks, there should be safe harbor conditions that account for the differences that may exist when these kinds of entities provide free or discounted transportation. In our view, the OIG should take into account the circumstances of a health system or provider network and should allow for transportation of patients among participants in such systems and networks. As noted above, in the preamble of the Proposed Rule the OIG describes an "established patient" very narrowly with respect to a practice group—i.e. a patient who has selected the "practice" and has attended an appointment with a physician "in the group". We believe that regulatory language describing the safe harbor should be broader and should allow for transportation of patients by providers within health systems and networks of providers.

Some of our members are structured as networks and provide a variety of programs, such as outpatient care, day hospitalization, and mental health rehabilitation, to name a few. A patient may be recently released from an inpatient or sub-acute care facility with debilitating symptoms or with chronic mental illness, which impairs their ability to independently function. We believe the safe harbor should allow for such a patient to be transported to another part of the network that can provide that patient with his or her next level of appropriate care.

c. Transportation Need and/or Financial Need and Related Documentation

The OIG solicits comments on whether to require entities offering free or discounted transportation "to maintain documented beneficiary eligibility criteria, such as a requirement that the patient show transportation need or financial need or that the transportation assistance would

address risks associated with failure to comply with a treatment regimen."[5] We certainly agree that the OIG needs to protect against arrangements under which, as stated in the Proposed Rule, patients could be offered free transportation based solely on number of appointments and without regard to transportation need. We also agree that it is reasonable to require an entity to have criteria in place with respect to the transportation needs and financial needs of the patient. However, such requirements and related requirements to maintain documentation should not be overly burdensome.

In the experience of our members, patients with psychiatric and addictive disorders are frequently not able to produce specific forms and documentation evidencing their finances. Yet, their financial need for assistance with transportation may be shown by the fact that they are on Medicaid or are dually-eligible beneficiaries. We would request that the OIG allow for a simple financial need assessment, which allows for entities to make reasonable assumptions about financial need where appropriate.

With respect to transportation need, we agree that the risk of failure to comply with a treatment regimen is one example of transportation need. We suggest that the OIG also specify that clinical need can show transportation need. The risk of failure to attend a scheduled appointment, for example, should be included, especially in the patient population that our members serve. Another factor evidencing transportation need could be the patient's psychiatric condition itself, or the medications that they are on (showing that they should not be driving, that they may be confused and incapable of managing public transportation, etc.). Not having the means to get to an appointment and, as a result, missing a psychiatric or behavioral health appointment, can have serious consequences.

d. Definition of "local" for purposes of eligible transportation

The OIG proposes to limit the safe harbor to "local transportation," and to explain that if "the distance that the patient would be transported is no more than 25 miles," then the transportation would be "deemed local."[6] The OIG solicits comment on whether this should be a fixed limitation, meaning no more than 25 miles would be considered "local" unless the final rule includes alternate tests, or whether the 25 miles should be "deemed" to comply with the safe harbor, meaning other distances could still comply with the requirement under appropriate facts and circumstances. We strongly believe that 25 miles should not be a fixed limitation and that it should not even be the relevant measure, at least in the context of specialized populations, including those with psychiatric and addictive disorders.

Many of our members serve patients who may not be within 25 miles of their facilities. This could be because of the specialized care that the patient requires or because the patient lives in a rural area. A beneficiary may need to travel 100-120 miles, for example, to get to the appropriate care that they require. In such cases, we do not believe that free or discounted transportation should be prohibited for this patient who shows financial and transportation need.

[5] 79 Fed. Reg. at 59723.
[6] Id. at 59724.

We support some of the suggestions that the OIG asked for comment on in the Proposed Rule and that are intended to address the fact that a distance-based test is not a one-size-fits-all solution. As noted above, we believe rural areas must be taken into account and provided increased flexibility. Likewise, flexibility beyond 25 miles should be allowed for underserved areas. The term "underserved" could be described with respect to the specific services provided in a given area, meaning that if there are few or no psychiatric service options in a given area, that area should be considered underserved for purposes of patients seeking psychiatric care.

Finally, as an overarching comment, we would suggest that the OIG address the unique needs of specialized patient populations separately in the safe harbor. Some specialized populations, such as patients undergoing cancer treatment or patients in need of treatment for their psychiatric or addictive disorders, for example, may need personalized transportation assistance over a much greater distance to safely access medically necessary care. Providers should be permitted to take reasonable measures as indicated by the patient's condition to accomplish such transportation. The measures should be evaluated on the totality of factors involved with deference given to accommodations for patient safety and support.

e. Interpretation of advertising for purposes of the safe harbor

We support the OIG's interpretation that signage on a vehicle designating the source of the transportation (e.g. the name of the hospital) should not be considered "marketing" or "advertising." Allowing for a vehicle to be marked with the organization's name is an important safety feature. There are patients who would not want to enter a vehicle that is unmarked.

In line with our comments above with respect to what types of patients the safe harbor should apply to, we would urge the OIG to clarify that, after appropriate assessment of financial and transportation need, informing a patient of the potential to receive free or discounted transportation would not be considered improper marketing or advertising.

III. Conclusion

As we have described above, this is an issue of critical importance to our members. In sum, we believe that a transportation safe harbor that is carefully constructed with thoughtful attention to the particular needs of specialized patient populations, and in particular, patients with psychiatric and addictive disorders, could be beneficial to beneficiaries. However, we also believe that a transportation safe harbor that is too narrowly construed would be harmful to the efforts of many psychiatric health providers in their efforts to serve a patient population that has unique and serious healthcare needs. Thus, we urge caution against creating a safe harbor that could inadvertently prevent or discourage the positive types of transportation assistance and services that the safe harbor is intended to support. We appreciate the OIG seeking input into its proposals and appreciate your time and consideration of our comments.

Again, we thank you for this opportunity to provider our input. Should you have any questions or concerns or if we can provide you with any additional information, please do not hesitate to contact me at 202/393-6700, ext. 100, or by email at mark@naphs.org.

Sincerely,

/s/

Mark Covall
President and CEO
National Association of Psychiatric Health Systems