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Advisory Opinion Allows Nurse Practitioner Support in Hospitals

On December 19, 2022, the *Department of Health and Human Services* (HHS) *Office of Inspector General* (OIG) published *Advisory Opinion* (AO) No. 22-20, analyzing the utilization of nurse practitioners (NPs) in lieu of attending physicians within medical units. The OIG concluded that the arrangement utilizing NPs in certain medical units, subject to several safeguards, presented a low risk for fraud or abuse.[1]

The OIG typically releases several AOs each year regarding their opinions on certain business arrangements – either existing or proposed – on which a party (such as a healthcare organization) has requested an opinion. An AO is the OIG's position on whether a certain business arrangement is in conflict with the federal Anti-Kickback Statute (AKS), one of the laws the OIG is charged with enforcing.

The AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[2] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[3] Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited. Consequently, the law has a number of exceptions, termed *safe harbors*,[4] which set out regulatory criteria that, if met, shield an arrangement from liability, and are meant to protect transactions unlikely to result in fraud or abuse.[5] However, failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[6]

Under the arrangement proposed to the OIG, the Requestor of the AO, an acute care hospital comprised of two campuses that provides both inpatient and outpatient hospital-based services, would provide NPs to assist in rendering certain care to patients of Participating Physicians, which patients are admitted or in observation status in two designated medical units.[7] The NPs would perform a wide range of tasks, some of which tasks the Participating Physicians would otherwise have to perform, including:

- Initiating plans of care through existing protocols;
- Implementing any applicable care protocols instituted by the hospital (e.g., stroke or community-acquired pneumonia protocols);
- Making rounds on assigned units, during which the NPs would address concerns of patients and their families, as well as those of nurses and other clinicians (e.g., physical therapists and speech therapists);
- Responding to laboratory or imaging studies, including arranging follow-up testing and attending to abnormal studies as needed;
- Addressing rapid changes in patient condition, including adjusting care plans and ordering imaging, laboratory tests, or other diagnostic tools or interventions in real time;
- Educating and supporting patients and families;
- Coaching, educating, and otherwise supporting nurses in the unit, including providing certified continuing education;
- Overseeing and supporting unit-based quality improvement projects; and
- Discharge planning, which at times may include obtaining insurance authorizations for post-acute care (such as for home health, skilled nursing, or acute inpatient rehabilitation) and scheduling follow-up testing and appointments.[8]

The aforementioned medical units subject to this agreement are general care units, i.e., not surgery or specialty care units (e.g., critical care, cardiology), and the Participating Physicians are predominantly primary care physicians.[9] From the experience of the hospital Requestor, having NPs readily available in these medical units improves patient care by allowing quick and efficient patient evaluations so that diagnoses can be received and treatment can be rendered as soon as practicable.

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As communicated to the OIG, the Requestor's proposed arrangement includes various safeguards, meant to protect against any fraud and abuse, including that:

- The NPs perform their duties in communication and collaboration with the Participating Physician treating the patient;
- The Participating Physician (or other qualified physician if the Participating Physician is unavailable) must still round daily, and Participating Physicians must maintain the same accountability as physicians who do not participate in this agreement;
- Participating Physicians are prohibited from billing for the services provided by NPs;
- Consistent with Medicare guidelines, Participating Physicians must conduct their own patient assessments and generate their own documentation in order to bill for services;
- The Requestor will pay for all services rendered by the NPs, and will not separately bill any payor, including Federal healthcare programs, for the NPs' services;
- Each year, the Requestor will send a letter to all physicians with privileges at the hospital who regularly admit patients to the two designated medical units, including physicians employed by affiliates of the Requestor and physicians employed by independent physician groups, informing them of the proposed arrangement;
- The Requestor will not take into account a physician's volume or value of expected or past referrals, nor will it target any particular referring physicians, when offering and providing NP services under this agreement;
- Payments will not be made to Participating Physicians, and there will be no ancillary agreements with Participating Physicians that would otherwise induce reward referrals to the Requestor; and
- Any compensation the Requestor pays to Participating Physicians outside of the proposed arrangement does not reflect or take into account any NP services performed.[10]

The OIG concludes its analysis by opining that this arrangement does implicate the AKS, specifically because the Requestor is providing remuneration in the form of in-kind NP services to Participating Physicians, which could induce such physicians to make referrals to the Requestor for items and services reimbursable by Federal healthcare programs. However, the OIG identifies three main reasons why this arrangement poses a minimal risk of fraud and abuse:

1. The arrangement is restricted to two non-surgical, non-specialty units at one of the Requestor's hospital campuses;
2. The arrangement contains safeguards that lower the risk of fraud and abuse under the AKS (e.g., duties performed by nurse practitioners are done so in communication and collaboration with Participating Physicians); and
3. The design of this arrangement appears unlikely to increase costs to federal healthcare programs and may ensure an appropriate level of care for patients within the aforementioned units.[11]

As noted by legal experts, this AO deviates from OIG's typical approach to limiting arrangements involving potential remuneration from a hospital to its referring physicians.[12] This deviation may be attributed to OIG's emphasis on healthcare providers offering quality care to Medicare and Medicaid beneficiaries.[13] In this case, the proposed arrangement's focus is on promoting quality and timely patient care, which is consistent with the OIG's push for value-based care.[14]

1 "Re: OIG Advisory Opinion No. 22-20" By Robert K. Deconti, Assistant Inspector General for Legal Affairs, Letter to [Redacted Name], December 14, 2022, https://oig.hhs.gov/documents/advisory-opinions/1062/AO-22-20_Ot53Mmd.pdf (Accessed 1/12/23)
2 "Criminal Penalties for Acts Involving federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
3 *Ibid*.
4 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, http://oig.hhs.gov/fraud/docs/advisoryopinions/15/AdvOpn15-10.pdf (Accessed 2/11/22), p. 5.
5 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" federal Register, Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520.
6 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf (Accessed 1/20/23), p. 1.
7 Deconti, Assistant Inspector General for Legal Affairs, December 14, 2022.
8 *Ibid*.
9 *Ibid*.
10 *Ibid*.
11 *Ibid*.
12 "OIG Approves Hospital Provision of Nurse Practitioner Services in Advisory Opinion" Bass Berry Sims, Firm Publication, January 5, 2023, https://www.bassberry.com/news/oig-hospital-provision-nurse-practitioner-services-advisory-opinion/ (Accessed 1/12/23).
13 *Ibid*.
14 *Ibid*.

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