OIG Advisory Opinion Approves Waiver of Charges for Indigent Cancer Patients

On September 4, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services released an Advisory Opinion allowing a non-profit hospital (Hospital) to waive:

- copayments and deductibles for patients with insurance, and
- all charges for uninsured patients who receive screening services and certain related follow-up services under an early detection program for breast and gynecological cancers (the "Waiver Policy").

Under the early detection program, if any therapeutic follow-up services are needed as a result of the screenings, care is usually provided at facilities not affiliated with Hospital. The Waiver Policy does not apply in the limited instances where such therapeutic follow-up care is provided at Hospital or Hospital-affiliated facilities.

The OIG approved the Waiver Policy because:

(i) indigent patients benefit from receiving preventive care they would otherwise not receive,
(ii) Hospital obtains limited financial benefit as a result of the policy due to the minimal amount of reimbursable follow-up services it provides and its refusal to accept payment for any referrals to other providers, and
(iii) two-thirds of the patients benefiting from the Waiver Policy are uninsured.

The Waiver Policy

The Services

Hospital operates a cancer center (Center) that provides an early detection program for breast and gynecological cancers. The program includes screening services (Screening Services) provided at Center, certain follow-up services (Follow-up Services) provided at Hospital-affiliated facilities, and related educational, counseling and referral services.

Screening Services include clinical breast exams, mammograms, Pap smears and pelvic exams. If an abnormal result is obtained from the Screening Service, the patient is called for Follow-up Services, such as biopsies, confirming tests and/or additional office exams, usually at Hospital facilities.

If concerns continue to exist after Follow-up Services are provided, the patient is then seen by one of the three Center surgeons for additional services, usually therapeutic in nature (e.g., surgery). As noted above, these additional therapeutic services are most often performed at facilities that are neither owned by nor affiliated with Hospital, and Hospital receives no remuneration for these referrals.

If the patient elects to have surgery or other additional therapeutic services at Hospital, the Waiver Policy ceases to apply.
Payment Policies
Center offers its early detection screening for breast and gynecological cancers at “no out-of-pocket expense” to patients. Center accepts third-party insurance, if any, as payment in full for the Screening Services and Follow-up Services. Thus, it waives out-of-pocket coinsurance expenses for patients with insurance and waives all charges for uninsured patients.7

Targets Indigent
Center targets its early detection program at members of the African and Hispanic community and publicizes the Waiver Policy as part of its outreach efforts to encourage use of the services. Approximately two-thirds of Center’s patients are uninsured, but small percentages are Medicare (5 percent) and Medicaid (12 percent) beneficiaries.

OIG Declines to Impose Sanctions
The OIG declined to impose sanctions under the Anti-Kickback Statute or under federal law prohibiting improper inducements to beneficiaries8 based on two aspects of the Waiver Policy that reduce the risk of fraud and abuse:

• Benefit to the uninsured
  The majority of the patients benefiting from the Waiver Policy are uninsured and would not otherwise receive the Screening Services and Follow-up Services. While some federal funds are used, private and Hospital donations subsidize the cost of care, and while some insured patients receive services under the Waiver Policy, the program is still fundamentally charitable. The OIG thus concludes that the services, coupled with the Waiver Policy, are unlikely to generate substantial remunerative services for Hospital, and sanctions are therefore not appropriate.

• Preventive services exception substantially satisfied
  Although the Screening Services do not qualify for the preventive care exception to the improper inducement statute because they are tied to non-qualifying services (see footnote 8), the non-qualifying Follow-up Services are limited to those necessary to confirm the screening test results. Therefor, the OIG believes that applying the Waiver Policy to the Follow-up Services is merely an extension of the provision of the Screening Services. Because the Waiver Policy does not apply to any additional therapeutic follow-up services provided at Hospital, and most such services are provided at non-Hospital facilities in any event, the OIG declines to impose sanctions.

Recommendations for Health Care Entities
Health care entities wishing to waive coinsurance or other charges for indigent and uninsured patients should review this Advisory Opinion and consult with counsel to properly structure such programs.

Programs should, at a minimum, be structured to:

• benefit indigent populations, such as the uninsured, for example, by providing services the patients would otherwise not receive;

• obtain funding from sources other than the federal fisc;

• avoid waiving coinsurance for screening services if the waiver is tied to the provision of services reimbursable by the Medicare or Medicaid programs;

• minimize any financial gain to the provider offering the program;

• minimize the potential for referrals to the provider offering the program; and

• preclude any payment for referrals made by the provider to other entities as a result of the program.
In addition, programs that meet, or substantially meet, the preventive care exception to the prohibition on inducements to beneficiaries statute also may pass scrutiny. Finally, the greater the percentage of indigents served, the better.

Conclusion
Thus, despite the potential risk of anti-kickback and improper inducement of beneficiaries violations, the OIG here permits the Waiver Policy because of the safeguards in place to minimize the risk to the Medicare and Medicaid programs and the benefit of providing preventive care to indigent populations.

1 Center accepts third-party insurance as payment in full for the services, so if no insurance exists, all charges are waived.
2 The Waiver Policy applies to screening services, such as mammograms and Pap smears, and certain related follow-up services, such as biopsies and confirming tests, that the OIG views as a mere extension of the initial screenings.
3 Advisory Opinion 01-14, Office of Inspector General, U.S. Department of Health and Human Services, dated August 27, 2001. The OIG declined to impose civil monetary penalties (CMPs) or exclusion sanctions against the Hospital offering the Waiver Policy.
4 Hospital operates a cancer center at its main campus and at a satellite facility (defined herein as the “Center”) in a nearby community. Center is operated as a division of Hospital and is funded by federal and state grants, private donations and grants from Hospital (to the extent required to meet annual operating costs). Center’s space is provided rent-free by the state.
5 Center surgeons are paid and credentialed by Hospital to provide services at Center, but they are not full-time physicians of Hospital. Rather, they maintain privileges at three nearby hospitals that are closer geographically to the areas where most Center patients live.
6 All Hospital standard billing procedures apply, including billing for coinsurance, except in cases of individualized determinations of financial need.
7 Screening Services and Follow-up Services are potentially reimbursable by Medicare and Medicaid. Under federal law, Medicare Part B deductibles may be waived for screening mammography and screening pelvic exams, but copays still apply. Under state Medicaid law, nominal copays apply for both Screening Services and Follow-up Services.
8 The Waiver Policy potentially violates both the federal Anti-kickback Statute and the federal statutory prohibition barring improper inducements to beneficiaries. Under the prohibition on improper inducements, the OIG may impose CMPs on a person who offers or transfers remuneration to a beneficiary that the person knows or should know is likely to influence the beneficiary to order or receive items or services from a particular provider, practitioner or supplier for which payment may be made by Medicare or Medicaid. “Remuneration” expressly includes waiver of coinsurance. See Social Security Act Section 1128A(a)(5); 42 CFR 1003.102(b)(13). The Waiver Policy does not meet an exception for preventive care services under the improper inducements to beneficiaries statute because the Screening Services are sometimes tied to delivery of certain non-preventive Follow-up Services reimbursable by Medicare and Medicaid, and because the Waiver Policy applies to certain services that do not meet the definition of preventive care. See 42 CFR 1003.101. The definition of preventive care services includes screening for breast cancer (clinical breast exam and mammography) and screening for cervical cancer (Pap smear).
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