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Client Alert News Flash

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OIG Solicits Comments Regarding New Healthcare Rules

OIG Proposed Rule to Expand Safe Harbors under the Anti-Kickback Statute and Exemptions under Civil Monetary Penalties Law

The Department of Health and Human Services, Office of Inspector General (OIG) released a proposed rule on October 2, 2014 (published in the Federal Register on October 3, 2014)[1] that would add new safe harbors to the Federal Anti-Kickback Statute (AKS),[2] expand exemptions from the definition of "remuneration" under the Civil Monetary Penalties Law (CMP)[3] and add a Gainsharing CMP provision to the regulations. The OIG is soliciting comments regarding this proposed rule until 5 p.m. Eastern Standard Time on December 2, 2014.

AKS Safe Harbor Expansion

The proposed rule will expand the AKS safe harbors to cover additional arrangements not previously protected. In addition to a technical correction to the existing referral services safe harbor,[4] new protections will apply to:

- Specific types of cost-sharing waivers, including:
    - Pharmacy waivers for financially needy patients under Medicare Part D
    - State or municipality owned emergency ambulance service waivers
- Certain arrangements between federally qualified health centers and Medicare Advantage organizations
- Manufacturer discounts on drugs furnished to patients under the Medicare Coverage Gap Discount Program
- Certain free or discounted local transportation services

Cost-Sharing Waivers

The proposed rule will add safe harbors for certain cost-sharing waivers. The new Part D cost-sharing waiver for pharmacies safe harbor mirrors an exception to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Under the proposed rule, a pharmacy waiving Part D cost-sharing will be protected under the safe harbor if: (1) waivers are not advertised; (2) waivers are not done routinely; and (3) the pharmacy makes a good faith determination that the beneficiary has a financial need.

An emergency ambulance service may waive cost-sharing if: (1) the service is operated by a State or federally recognized Indian tribe and is a Medicare Part B provider or supplier; and (2) the waivers are applied uniformly.

Medicare Advantage Arrangements and Medicare Coverage Gap Discount Program

The proposed rule will also allow a Medicare Advantage (MA) enrollee to receive services from a federally qualified health center (FQHC) that has a written agreement with a MA plan. In order to be protected, the MA organization must pay the FQHC at least the amount of payment the MA organization would make for the same services if they were performed by a different entity.

Additionally, discounts in the price of an "applicable drug"[5] of a manufacturer that is furnished to an "applicable beneficiary"[6] under the Medicare Coverage Gap Discount Program would be protected, so long as the manufacturer participates in, and is in full compliance with all requirements of, the Medicare Coverage Gap Discount Program.

Local Transportation

The OIG also proposes to create a new safe harbor for certain free or discounted local transportation arrangements. Such services must meet a number of conditions to qualify for the safe harbor, including:

- The service must be provided by an "Eligible Entity." The Eligible Entity would not include durable medical equipment suppliers and pharmaceutical companies, and potentially, laboratories. The OIG is also considering excluding home health care providers if the services are furnished to a referral source.
- The discounts or free services must only be provided to established patients of the Eligible Entity.
- A determination of services must be unrelated to past or anticipated volume or value of federal health care program business.
- The free or discounted transportation must not be based on the type of treatment.
- The Eligible Entity may potentially be required to maintain documented beneficiary eligibility criteria.
- The Eligible Entity may potentially be allowed to transport patients for purposes other than direct healthcare, as long as the service is related to the patient's health, such as applying for government benefits, obtaining counselling or getting to food banks.

The transportation would need to remain local (*i.e.,* no more than 25 miles), and the safe harbor would not include luxury transportation. In addition, the Eligible Entity would be required to bear the costs of the transportation and not pass the costs to other payors, including Medicare and other federal health care programs. The OIG is also considering other limitations, such as limitations on marketing or advertising by Eligible Entities relating to the services.

CMP Exceptions to Remuneration

Beyond the addition of the AKS proposed safe harbors discussed above, the OIG proposed rule would add exceptions to the regulations addressing the CMP prohibitions against offering inducements to Medicare or Medicaid beneficiaries that the offeror knows or should know are likely to influence the selection of particular providers, practitioners or suppliers. One proposed exception would exclude from the definition of "remuneration" a hospital's reduction in the copayment amount for covered hospital outpatient department (OPD) services to no less than 20 percent of the Medicare OPD fee schedule

amount and follow the procedures set forth under current regulations. Pursuant to 42 C.F.R. 419.42, hospitals may elect to reduce coinsurance for any or all APC groups on a calendar year basis, so long as 1) the hospital notifies its Medicare Administrative Contractor of its election no later than December 1 preceding the beginning of each subsequent calendar year, 2) the reduced copayment is for all services within the same APC group, and 3) any reduced copayment amount may not be further reduced or increased during the year involved. The hospital is permitted to advertise and otherwise disseminate information concerning the reduced level of coinsurance that it has elected, provided that all advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

The OIG also proposed adding four new subparagraphs protecting certain charitable and other programs by adding them as exceptions to the definition "remuneration." New exceptions to the definition include:

- Remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs would not be prohibited
- Certain retailer rewards, as long as the reward:
    - Is a coupon, rebate or other reward
    - Is equally available to the public, regardless of health insurance status
    - Is not tied to the provision of other items or services reimbursed by Medicare or state health care programs
- Offering or providing services for free or less than fair market value when the recipient qualifies due to financial need
- Waivers by a Prescription Drug Plan sponsor of a Part D plan or MA organization offering MA-PD plans of any copayment that would be otherwise owed by their enrollees for the first fill of a covered Part D drug that is a generic drug

Gainsharing

Finally, the OIG recognizes that as hospitals move towards using objective quality metrics, certain practices that facilitate such metrics and accountability for performance do not necessarily constitute a limitation or reduction of services but an improvement in patient care or a reduction in cost without reducing patient care or diminishing its quality. Accordingly, the OIG is seeking comments on the following topics:

- Is the OIG's current interpretation of the prohibition on payments to reduce or limit services as including payments to limit items used in providing services appropriate or necessary in the context of the Gainsharing CMP?
- Should a hospital's decision to standardize certain items (*e.g.*, surgical instruments, medical devices, or drugs) be deemed to constitute reducing or limiting care? Would the answer be the same if the physicians were simply encouraged to choose from the standardized items, but other items remained available for use when deemed appropriate for any particular patient?

- Should a hospital's decision to rely on protocols based on objective quality metrics for certain procedures ever be deemed to constitute reducing or limiting care (*e.g.*, protocols calling for the discontinuance of a prophylactic antibiotic after a specific period of time)? Should hospitals deciding to compensate physicians in connection with the use of such protocols be required to maintain quality-monitoring procedures to ensure that these protocols do not, even inadvertently, involve reductions in care? What types of monitoring and documentation would be reasonable and appropriate?

- Should a hospital desiring to standardize items or processes as part of a gainsharing program be required to establish certain thresholds based on historical experience or clinical protocols, beyond which participating physicians could not share in cost savings (*i.e.*, change beyond the relevant threshold would be deemed to constitute reducing or limiting services)?

- If the OIG defines ''reduce or limit services,'' should the regulation include a requirement that the hospital and/or physician participating in a gainsharing program notify potentially affected patients about the program? Would such a requirement help ensure that gainsharing payments were for legitimate purposes and not for the purpose of reducing or limiting care?

Conclusion

Given the potential implications of the proposed rule, we suggest that you consider submitting comments and making recommendations to the OIG on the new proposed AKS safe harbors and/or CMP exemptions. We would be happy to assist you in reviewing or drafting a comment letter prior to submission.

If you have questions about this *Client Alert* or are interested in submitting a comment letter, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

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Endnotes

1 Medicare and State Health Care Programs, 79 Fed. Reg. 59717 (Oct. 3, 2014).

2 42 U.S.C. § 1320a–7b(b).

3 42 U.S.C. § 1320a–7a(a)(5).

4 The OIG proposed to make a technical correction to the safe harbor for referral services, found at 42 C.F.R. § 1001.952(f). The safe harbor originally required that any referral fee service be charged "based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by the participants for the referral services…." In 1999, the language was modified, changing "the participants" to "either party for the other party." *See* Medicare and State Health Care Programs, 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999). During subsequent revisions to the safe harbor, this language was lost, but the proposed rule would revert back to the language from the 1999 rule.

5 "*Applicable drug* means, with respect to an applicable beneficiary, a covered part D drug — (a) approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and (B)(i) if the sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; (ii) if the [prescription drug plan (PDP)] sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or (iii) is provided through an exception or appeal." 79 Fed. Reg. 59717, 59721 (Oct. 3, 2014).

6 "*Applicable beneficiary* means an individual who, on the date of dispensing a covered part D drug — (A) is enrolled in a prescription drug plan or [a Medicare Advantage Prescription Drug (MA–PD)] plan; (B) is not enrolled in a qualified retiree prescription drug plan; (C) is not entitled to an income-related subsidy under section 1860D–14(a); and (D) who — (i) has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) during the year; and (ii) has not incurred costs for covered part D drugs in the year equal to the annual out of- pocket threshold specified in section 1860D–2(b)(4)(B)." *Id.*