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OIG's Proposed Safe Harbors and CMPL Rules: A Different Way of Thinking?





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Introduction

On Oct. 3, the Department of Health and Human Services Office of Inspector General proposed regulations (proposed rule) that would amend its regulatory anti-kickback statute (AKS) safe harbors and the definition of ''remuneration'' under the civil monetary penalty law (CMPL) related to beneficiary inducements and gainsharing.

The proposed rule evinces OIG's struggle in finding the right balance between issuing narrowly tailored rules to protect patients against abusive conduct while not stifling the growth of beneficial arrangements designed to increase or improve access to care, including better care coordination.

The proposed rule also seeks to incorporate in regulation a number of statutory requirements from the Affordable Care Act (ACA) and Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), some of which have been outstanding for over a decade.[1]

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HHS Inspector General Daniel R. Levinson

Public comments to the proposed rule are due by Dec. 2. The OIG has gone to great lengths to implore health-care stakeholders, including health-care lawyers, to submit comments on the more thorny issues concerning the interplay of these fraud and abuse laws with the post-health reform landscape of improved care coordination and innovative payment arrangements.

[1] The proposed rule implements a new safe harbor as 1001.952(z) for the statutory exception enacted in the MMA to 42 U.S.C. Section 1395w-27(e) for arrangements between Federally Qualified Health Centers and Medicare Advantage Plans, providing details for the safe harbor in protecting remuneration via written agreements. The proposed rule similarly implements a safe harbor for the statutory exception as 1001.952(aa), enacted by ACA to protect discounts associated with the Medicare Coverage Gap Discount Program and provides definitional requirements for the qualifying terms ''applicable drug'' and ''applicable beneficiary.'' The proposed rule does not substantively change the statutory exceptions already enacted in the respective legislative provisions or forecast significant changes to existing or future arrangements.

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In fact, OIG seeks the public's input and comments no less than 48 times in the proposed rule. As HHS Inspector General Daniel R. Levinson noted in an Oct. 6 keynote address before the American Health Lawyers Association, ''Give us your best thinking on how to craft these rules. . . . There's a different way of thinking about how health care should be delivered.''[2]

The OIG is charged with considering from time to time changes or additions to the safe harbor regulations with a goal ''to protect beneficial arrangements that enhance the efficient and effective delivery of health care and promote the best interests of patients, while also protecting the Federal health care programs and beneficiaries from undue risk of harm associated with referral payments.''[3]

Accordingly, some of the proposed changes to the AKS safe harbor regulations and the definition of ''remuneration'' under the CMPL for beneficiary inducements and gainsharing arrangements involve thoughtful consideration of a rapidly evolving health care delivery system. Many new and innovative arrangements have already taken root in the health care market.

The OIG recognizes this and solicits significant industry input that could reduce the risk that the OIG narrowly interprets those ACA provisions and stifles innovation, even though the voluminous feedback the OIG may received may delay final rulemaking.

Notably, the OIG and the CMS recently extended their Accountable Care Organization (ACO) CMPL waivers for another year, suggesting that health care regulators are deeply committed to promoting innovative methods of furnishing health care – thus, the proposed rule dovetails with OIG's efforts in other areas of the health care industry.[4] This article discusses many of the proposed rule's safe harbor and CMPL changes.

AKS Safe Harbor Proposed Changes

1. *Cost-Sharing Waivers*

As Medicare expends considerably more on its Part D benefit, scrutiny of such payments has increased. Beneficiary cost-sharing (e.g., co-pays, coinsurance and deductibles) is an important part of plan design and the routine waiver of such cost-sharing obligations may implicate the AKS and CMPL. Although unstated in the proposed rule, potential violations of the AKS may also implicate the federal False Claims Act given that AKS compliance is a condition of payment.[5] Congress amended the AKS in the MMA to add a statutory exception for certain pharmacy cost-sharing waivers. These exceptions are reflected in the CMPL and explain that a pharmacy waiver is protected if:

> (i) the waiver is not offered as part of any advertisement or solicitation;
>
> (ii) the person does not routinely waive coinsurance or deductible amounts; and
>
> (iii) the person—
>
> (I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
>
> (II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts.[6]

OIG's proposed safe harbor would provide a ''deeming'' mechanism for cost-sharing waivers for Part D subsidy-eligible beneficiaries (commonly referred to as low-income subsidy (LIS)[7] customers who have income below 150% of the poverty line) who also meet certain resource requirements.

The proposed rule's safe harbor change for cost-sharing waivers simply incorporates the statutory exception, and is one of several instances in the proposed rule where providing free or reduced cost items or services to beneficiaries is protected, but where providers are prohibited from advertising or promoting the benefit.

Although the ''no advertising'' standard is in the statute, this creates a vexing situation for providers inasmuch as OIG has interpreted advertising to include ''word of mouth'' advertising.[8]

So the lines are anything but clear on how providers—in this case, pharmacies—should best operationalize cost-sharing waivers or other programs designed to assist financially needy beneficiaries.

2. *Free or Discounted Local Transportation*

In the context of the CMPL beneficiary inducement provisions, OIG has considered whether to protect free or subsidized local transportation for beneficiaries since 2000.

While it recognizes the important benefits that may flow from free local transportation (e.g., beneficiary convenience, increased access to needed health care services, and the possibility of reducing Medicare and Medicaid program costs), the OIG is equally cognizant of the risk of abuse or patient steering presented by the provision of free or discounted transportation.

In the proposed rule, the OIG proposes a new AKS safe harbor for free or discounted local transportation, which would also immunize such protected arrangements from CMPs since the definition of ''remuneration'' under the CMPL excepts safe harbored arrangements.[9]

The OIG views this as regulatory quicksand, soliciting public input on a wide variety of issues relating to the proposed safe harbor.

The OIG observes in the proposed rule that the beneficiary inducement law's legislative history demonstrates that Congress did not intend the statute to preclude the provision of complimentary local transportation of a nominal value.[10]

[2] BNA Health Care Fraud Report, Oct. 6, 2014 (by James Swann).
[3] 79 Fed. Reg. 59717, 59719 (Oct. 3, 2014).
[4] *See* 79 Fed. Reg. 62356 (Oct. 17, 2014).
[5] 42 U.S.C. § 1320a-7b(g).
[6] SSA § 1128A(i)(6)(A).
[7] *See* SSA § 1860D-14(a)(3).
[8] OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, published in 67 Fed. Reg. 55855, 55857 (Aug. 30, 2002).
[9] 79 Fed. Reg. at 59722.
[10] H.R. Conf. Rep. No. 104-736 at 255 (1996).

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Should the OIG adopt clear, bright line criteria, like a 25-mile limit to define ''local,'' even in rural areas? Should free or discounted transportation be available for only established patients? May a transportation program be limited to only network providers? Should transportation be limited to medical services or extend to related purposes (e.g., to apply for government benefits, to obtain social services, etc.)? Should the OIG permit a shuttle service serving a route that includes local physician offices/referral sources, even if the shuttle picks up new patients?

The OIG solicits comments on these and many more questions regarding the scope of the safe harbor, aware that local transportation programs in health care abound (and have for years), but ever hesitant to overextend safe harbor protections.

Under its proposed safe harbor, OIG would protect:

- free or discounted local transportation, excluding luxury or ambulance transports, not determined in a manner related to past or anticipated volume or value of Federal health care program business
- to established patients (and an accompanying person)
- to obtain medically necessary items and services
  - o if the transportation services are not marketed or advertised and no marketing occurs during transport
  - o if the drivers are not paid a per-beneficiary transport fee, and
  - o if the costs of the transportation are not shifted back to a government program.
- OIG also solicits public comment on protecting a form of shuttle service.

In its proposal, OIG seeks to protect only transportation offered by an ''Eligible Entity,'' defined to exclude entities that primarily supply health care items (i.e., durable medical equipment suppliers, pharmaceutical manufacturers and laboratories), as distinguished from health care providers that primarily furnish health care services. OIG expresses concern that ''suppliers'' would use transportation programs to steer patients and generate business for themselves, whereas providers of services have broader patient care responsibilities.

Recognizing that the definition of ''Eligible Entity'' is critical to safe harbor protection, OIG solicits comment on which entities should be included in the definition, suggesting that those provider sectors with a history of overutilization (e.g., home health) be excluded when transporting patients to or from referral sources (e.g., doctor's offices).

The OIG also solicits input on whether there should be additional safeguards depending upon the type of entity providing the transportation and, if so, what those safeguards should be. Given the wide variety of health service providers, this could lead to a complex and potentially confusing safe harbor that may do little to enhance beneficiary access to appropriate health care services.

In addition, the OIG solicits input on whether safe harbor protection should be extended to patients who have selected a provider, but have not yet started receiving services from that provider, as distinguished from established patients (as it currently proposes). The proposed rule would not extend safe harbor protection to transportation programs for new patients.

The OIG also will not extend safe harbor protection to transportation programs that are limited to transport from or to certain referral sources or that tie the transport to the volume or value of referrals. The OIG muses whether a transportation program based on the number of appointments creates a linkage to volume of Federal health care program business.

The OIG also struggles with allowing provider networks or health systems to limit free transportation programs to within its network, seeking comments on whether and how it should do so and potential safeguards. Similarly, the OIG struggles with permitting transportation programs tied to the type of treatment a beneficiary may receive, concerned that if such programs are limited only to expensive and lucrative treatments, they may become abusive.

Would the OIG look to the profit margin of a treatment in extending safe harbor protection? What if one provider has a significant profit margin on a high cost treatment and the other (e.g., a teaching hospital) loses money on that service line? Nevertheless, the OIG proposes to extend protection to transportation provided on the basis of specific conditions (just not specific treatments for those conditions).

The OIG solicits comments on other transportation safe harbor limitations, such as public advertising and marketing to patients and referral sources, paying drivers on a per-beneficiary basis, and prohibiting marketing of health-care items and services during transportation even if signage designating the source of transportation would be permitted.

For example, would an advertisement of a network pharmacy on health system's shuttle bus eliminate the program from safe harbor protection? If the OIG ultimately adopts a very prescriptive safe harbor with different criteria for different provider types and different service lines, such an approach has the makings of a complex and potentially unworkable safe harbor.

Given that health care providers are bound by myriad other fraud and abuse requirements designed to protect beneficiaries and the Medicare/ Medicaid programs, the OIG should consider whether an overly complex local transportation safe harbor is appropriate, especially if it stifles these programs that benefit patient access to care.

CMPL ''Remuneration'' Exceptions

1. *Beneficiary Inducements*[11]

a. Remuneration Promoting Access to Care and Posing a Low Risk of Harm

The ACA added a catchall exception to the definition of ''remuneration'' for ''any other remuneration which

[11] In addition to those sections specifically delineated in the proposed rule, the OIG also proposes to codify a statutory exception to the definition of ''remuneration'' under the CMP added by Section 4523 of the Balanced Budget Act of 1997, which excluded from the definition of ''remuneration'' a reduction in the hospital copayment amount for covered outpatient services as long as the charged copayment amount is no less

promotes access to care and poses a low risk of harm to patients and Federal health care programs.'' In a nod to the possible breadth of this statutory exception, the OIG did not propose any regulatory text for this exception. Rather, OIG requested proposals for regulatory text, emphasizing the need for specific examples of the types of remuneration to beneficiaries that should be excepted.

While the OIG did not propose regulatory text, it laid out its views in the preamble regarding appropriate principles for a future exception, along with multiple requests for examples of inducements that should meet the exception and reactions to the OIG proposals. Specifically, the OIG proposed to interpret the first prong of the statutory exception—i.e., the phrase ''promotes access to care''—as meaning that the ''remuneration provided improves a particular beneficiary's ability to obtain medically necessary health care items and services.''[12]

The OIG also offered a broader, alternative interpretation for the phrase ''promotes access to care '' that would include ''encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient than it would otherwise be.''[13]

The OIG specifically requested reaction to these different approaches, including examples of remuneration that would meet the broader interpretation of the phrase, but not the narrower approach. The OIG reminded potential commenters that remuneration that is not likely to influence a beneficiary to order or receive items or services from a particular provider or supplier need not meet an exception.

The OIG also noted it is considering whether the exception should require the remuneration be aimed at a particular beneficiary or a ''defined beneficiary population (such as beneficiaries being treated under a designated care protocol).''[14] In addition, the OIG requested comments on whether the word ''care'' should refer only to a patient's medical care (versus non-clinical care, such as social services).

The OIG specifically requested reaction to these different approaches, including examples of remuneration that would meet the broader interpretation of the phrase, but not the narrower approach.

For the second prong of the statutory exception, the OIG proposed to interpret the phrase ''low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs'' to mean that the ''remuneration: (1) is unlikely to interfere with or skew clinical decision-making; (2) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) does not raise patient safety or quality-of-care concerns.''[15]

The OIG noted it had approved some arrangements through its advisory opinion process that met both requirements of the statutory exception (e.g., the provision of subsidized lodging by hospitals to patients and their families when the assistance was necessary for the patient to obtain care).

The OIG also offered examples of items that are necessary for patients to record health data (e.g., blood pressure cuffs or scales) that could meet the dual requirements of promoting access to care and raising only a low risk of harm to beneficiaries and the programs, so long as receipt of the items is not conditioned on the patient obtaining other items or services from a particular provider.

Nonetheless, the OIG expressed its skepticism with providers' offering valuable gifts to beneficiaries in connection with marketing activities, or ''rewards'' given by suppliers and providers to patients, in the OIG's words, ''purportedly'' for compliance with treatment regimens when the offeror knows or should know the rewards are likely to influence the recipients to order or receive items or services from a particular source.[16]

The OIG asks a series of questions regarding incentives for compliance and seeks comments regarding what limitations and safeguards or monitoring mechanisms should be in place to protect against ''abusive arrangements that increase costs or compromise quality.''[17] The OIG also requests comments on other types of remuneration not mentioned in the proposed rule that providers are using to foster patient engagement which promote access to care and pose a low risk of harm to beneficiaries and the programs. We believe this area will be particularly important for comments.

b. Coupons, Rebates, and Other Retailer Reward Programs

Though billed as the mere codification of statutory requirements, the OIG's proposal to implement the exception to the definition of ''remuneration'' for retailer rewards programs warrants careful consideration. This is all the more true by the reach and market power of the entities that will likely seek to rely on this exception in the future (i.e., ''big box'' retailers, chain pharmacies, and supermarket conglomerates).

ACA set forth an exception protecting:

The offer or transfer of items or services for free or less than fair market value by a person, if—

(i) the items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under

than 20 percent of the Medicare outpatient fee schedule. In short, OIG proposes to adopt at 42 C.F.R. 1003.110 language identical to the statutory language at SSA 1128A(i)(6)(E), with one minor correction.

[12] 79 Fed Reg. at 59725.

[13] *Id.*

[14] *Id.*

[15] *Id.* at 59726.

[16] *Id.*

[17] *Id.*

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title XVIII or a State health care program (as defined in section 1128(h)).[18]

Regarding the first requirement, the OIG will interpret the term ''retailer'' as having its usual meaning (e.g., an entity that sells items directly to customers), but the OIG notes that retailers do not include entities that primarily provide services to customers, such as hospitals and physicians. The OIG solicits comments on whether entities that primarily sell items which require a prescription (e.g., medical equipment stores) should be considered retailers. It may be important for retail pharmacies to request clarification from the OIG that they are considered ''retailers'' for the purposes of the exception.

The OIG does not explicitly address whether certain services provided by retailers, including pharmacies, may qualify for retailer rewards, but this issue may become critical as more retailers establish and expand retail clinics. For example, is it permissible for retailers to offer loyalty program points based on any co-payment obligation for services provided by the retailer (e.g., the provision of a flu shot) or in a retail clinic operated by the retailer? Given the inconsequential value of such reward points, the risk of abuse through such programs remains low. Perhaps it is telling that the OIG explains ''[m]any retailers offering such programs have pharmacies that sell items or *services* reimbursable by Federal health care programs.''[19] Is the invocation of the word ''services'' intended to mean that reward points for retail clinic services are allowed?

Regarding the second requirement, the OIG recites its long-standing policy that Medicare providers and suppliers cannot discriminate against or ''cherry-pick'' certain patients based on health insurance status. As an example, the OIG warns that a retailer that targets its reward program to Medicare beneficiaries only would not meet this condition. Conversely, a retailer mailing a $10 coupon off the next purchase of any item in the store, including prescriptions, to all the residents of a zip code area would, according to the OIG, meet the second requirement of the exception.

But would this coupon continue to meet this second requirement if a large segment of the retailer's customers could use the coupon to satisfy his or her co-payment obligation for a prescription? For example, a Medicare beneficiary could use the coupon to pay his or her co-payment obligations on items and services reimbursed in whole or in part by Medicare, but it is likely that a customer with a commercial prescription insurance benefit could not benefit from the coupon in the same way. Commercial provider agreements between the pharmacies and a commercial insurance plans typically require pharmacies to collect all co-payment obligations from insured members.

Finally, the third requirement of the exception will be met so long as there is no link between federally payable items and services and a loyalty program's rewards, both in the manner in which the rewards are earned and the manner in which the reward is redeemed. Thus, so long as both the ''earning'' and ''redeeming'' side of the transaction do not specifically compel the purchase of items or services covered by Federal health care programs, retailers should have broad discretion in how they choose to promote their businesses.

c. Financial-Need-Based Exception to Definition of Remuneration

ACA also carved out from the definition of ''remuneration'' the offer or transfer of items or services for free or at less than fair market value after a determination the recipient is in financial need and meets certain other criteria.[20]

The OIG first notes that the ''items or services'' which may be excluded from the definition of ''remuneration'' cannot include cash or ''instruments convertible to cash,'' such as checks. In addition, like other exceptions to the definition of ''remuneration'' created by ACA, these items or services may not be offered as part of an advertisement or solicitation, a requirement that may substantially limit how widespread and frequent these offers may occur and be protected.

The OIG also notes that there cannot be a link between the offer and ''other services'' reimbursed in whole or in part by Medicare or Medicaid. The OIG intends to interpret this linkage through a ''reasonable connection'' test to the ''medical care'' of the beneficiary. Under the proposed rule, it is possible to avoid a ''reasonable connection'' even if there is not a ''complete severance of the offer from the medical care of the individual,'' but that conditioning the offer or transfer on the beneficiary's use of other Medicare- or Medicaid-reimbursed services would violate the CMPL.

The OIG solicits input on its interpretation of this link, as it appears to recognize the lack of clear guidance on the contours of what may constitute a ''reasonable connection.'' The OIG proposes that a ''reasonable connection'' exists from a ''medical perspective'' when items or services would benefit or advance identifiable medical care or treatment that the patient is receiving. This suggests a ''reasonable clinician'' standard.

The OIG also poses that a ''reasonable connection'' would not exist from a ''financial perspective'' if the remuneration is disproportionately large compared with the medical benefits conferred on the patient in order to induce the patient to obtain additional services. This suggests assigning an economic value to the medical benefits the patient receives. Would that be best measured by the reimbursement received by the provider? In a health reform environment, this concept merits public comment.

The proposed rule provides for a highly individualized determination for transfer of free or reduced charge items that is dependent upon the context of the patient's medical care. Items or services not reasonably connected to an individual's medical care that are not ''medically indicated'' would not be covered under this exception. A free air conditioner to an asthmatic patient may qualify, but would the same item distributed to a frail 94 year old in Florida also qualify? Recognizing the quagmire such ambiguity may create, the OIG solicits comment ''on the boundaries of the concept of 'medically indicated.' ''[21]

The OIG also solicits comment on whether one condition of meeting this exception should be that a health care professional has concluded that the items or services would benefit the individual patient's treatment or

[18] ACA § 6402(d)(2)(B)
[19] 79 Fed. Reg. at 59726.
[20] *See* SSA § 1128A(i)(6)(H).
[21] 79 Fed. Reg. at 59728.

other unique indicators, such as the availability of health care facilities in the community and ''unique physical, behavioral or mental health issues that might interfere with the patient's access.''[22] Again, this suggests documentation of individualized determinations on how the items or services are reasonably connected to the patient's medical care will be essential, which could create compliance challenges for providers.

The last requirement of this statutory exception interpreted by the OIG is that there must be a ''good faith'' determination that the individual is in financial need. Again, the OIG proposes to require an individualized assessment of financial need on a ''case-by-case basis.'' To the extent income guidelines are used, OIG notes they should be based upon objective criteria for the applicable locality. National providers would thus have to use local standards.

The OIG also notes that ''financial need'' not be limited to ''indigence'' and that individualized variables may be appropriately considered. Last, OIG suggests it would be ''prudent'' to maintain accurate and contemporaneous documentation of the financial need assessment and criteria applied.[23] Again, this may provide compliance and operational challenges for providers to develop robust documentation systems for individualized determinations of financial need.

2. *Gainsharing*

The gainsharing CMP prohibits hospitals (including critical access hospitals) from knowingly paying a physician to induce him or her to reduce or limit services provided to Medicare or Medicaid beneficiaries under the physician's care.

Nonetheless, in proposing rules to govern the changing health care landscape that places greater emphasis on accountability and providing high quality care at lower costs, the OIG seems to accept that there are frequent instances where incentive payments between doctors and hospitals can have legitimate cost-saving effects without compromising the integrity of furnished health care services.

Balancing this reality with its obligations to abide by statutory authorities (i.e., ''The statute does not prohibit only payments to reduce medically necessary services; it prohibits payments to reduce or limit 'services'.''), the OIG has proposed to interpret the phrase ''reduce or limit'' services in the gainsharing CMP statute to allow for incentive payments from hospitals to physicians in the course of implementing formularies, standardized protocols, and similar cost-saving mechanisms.[24]

Specifically, the OIG reverses course on its prior assertions made in various Advisory Opinions and instead recognizes that ''a change in practice does not necessarily constitute a limitation or reduction of services, but may in fact constitute an improvement in patient care or a reduction in cost without reducing patient care or diminishing its quality.''[25]

It therefore proposes to narrow the gainsharing CMP to better focus on instances of improper discharges or other actions that ''inappropriately'' limit a patient's care. Of course, it is difficult for the OIG to object to more innocuous gainsharing arrangements—the type that would be protected under the proposed exception—when the federal government has largely encouraged distribution of cost-savings through ACOs and similar health management programs.

Consistent with the trend in innovative cost-saving arrangements, the OIG openly acknowledged that it has never pursued a gainsharing CMP case and that such pursuit remains a low enforcement priority.[26]

The OIG's handling of its CMP authority portends a reduction in regulatory risk when arrangements can save costs to Federal health care programs while maintaining or improving quality of care. It also displays the OIG's ability to reinterpret statutory authorities to keep pace with the rapidly developing health care industry.

However, it is important to consider that the OIG still requires that hospitals use objective metrics to ensure that quality and cost-saving data points are legitimate and verifiable. In addition, the OIG has proposed and will likely finalize some type of thresholds in the gainsharing exception related to historical experiences beyond which physicians may not share in savings.

While the shape of the OIG's proposed exception remains uncertain, it solicits comments in a number of areas to better understand how the health care industry embraces gainsharing arrangements. Specifically, the OIG asks whether it should:

- penalize a hospital for standardizing care if it does not also allow physicians to use other items when deemed appropriate for any particular patient;
- penalize a hospital in any circumstance if its clinical protocols are based on objective quality metrics, particularly if the hospital operates a quality monitoring program;
- set forth certain types of quality monitoring and documentation that will be deemed appropriate to ensure no reduction or limitation in services occurs;
- require hospitals and physicians participating in gainsharing arrangements to notify potentially affected patients; and
- interpret the prohibition on payments to reduce or limit services to also include items (note that this solicitation is incongruous with other provisions of the proposed rule, particularly those in which the OIG declines to broaden services to include items. The agency should interpret services in a consistent manner without consideration of the various authorities to which it might apply).

Several of the issues on which the OIG solicits comments are relatively common and it is important that providers benefiting from these arrangements inform the OIG of the importance of protecting these well-accepted practices.

As alternative payment mechanisms continue to develop and evolve, the same considerations that the OIG uses in its gainsharing arrangement will likely be applied across the board to control costs and increase health care quality.

Conclusion

The OIG's proposed rule, while mostly remaining true to the underlying statutory requirements, raises a

[22] *Id.*
[23] *Id.*
[24] *Id.* at 59729.
[25] *Id.* at 59730.
[26] *Id.* at 59729.

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number of important considerations for providers engaged in innovative care models.

Those portions of the proposed rule in which the OIG provides substantive interpretation of the AKS and CMPL authorities appear to tip the agency's hand regarding the future of its enforcement agenda. Indeed, health care providers that can legitimately reduce costs without sacrificing quality should have relatively unfettered ability to run their programs without significant the OIG scrutiny.

Nevertheless, it remains to be seen how the public's reaction to the OIG's proposals will affect the agency's thinking. It may be years until the OIG actually internalizes those recommendations and finalizes its rule. In the meantime, it is clear that the industry will continue to evolve in the face of budget and compliance challenges.