

Bundled Payments and Other Risk Arrangements for Post-Acute Care Providers

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Agenda

- Bundling arrangements
- Fraud and abuse considerations affecting bundling arrangements
- Bundling waivers under Federal Anti-Kickback Statute and Stark
- Collaboration/Contract Issues
- Swapping and fair market value
- What's Next?



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Affordable Care Act (ACA) and Coordinated Care Initiatives

- The Centers for Medicare & Medicaid Innovation ("The CMS Innovation Center") was created by §3021 of the ACA (amending § 1115A of the SSA)
 - For purpose of testing "innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care."
 - Model must either reduce spending without reducing the quality of care, or improve the quality of care without increasing spending, and must not deny or limit the coverage or provision of any benefits.

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<h2>ACA and Coordinated Care Initiatives</h2>		
<ul style="list-style-type: none">• CMS Innovation Center https://innovation.cms.gov/initiatives/index.html#views=models• Past and Present Innovation Center Programs:<ul style="list-style-type: none">• Nursing Home Value-Based Purchasing Demonstration• Physician Group Practice Transition Demonstration• Comprehensive Primary Care Initiative• Accountable Care Organizations (ACO)• Bundled Payments for Care (BPCI)		
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<h2>The ACA Established ACOs</h2>		
<ul style="list-style-type: none">• ACO - An organization of health care providers that agrees to be:<ul style="list-style-type: none">▪ Accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it▪ Share in the savings such activities generate for Medicare▪ Financially responsible should costs exceed certain benchmarks• As of August 2016, ACOs have generated more than \$1.29 billion in total Medicare savings since 2012.• A University of Michigan Population Studies Center research project is examining the impact of ACOs on post-acute care utilization; and the impact of changes in post-acute care spending and utilization on patient outcomes.		
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<h2>The ACA Established ACOs</h2>		
<ul style="list-style-type: none">• Examples:<ul style="list-style-type: none">▪ Pioneer ACO Model▪ Medicare Shared Savings Program ("MSSP") ACO Model▪ Next Generation ACO Model▪ ACO Investment Model (AIM)▪ Medicare-Medicaid ACO Model (Dec 15, 2016)		
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Overview of Bundled Payments



Bundled Payment - Medicare offers a single lump sum for an entire episode of care related to a treatment or condition and that sum is then divided among all parties who provide services during that episode of care.

- 1991: coronary artery bypass graft surgery demo (CABG)
- 2009: Acute Care Episode (ACE)
- 2016: Oncology Care Model (OCM)

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Bundled Payment v. ACO

Bundled Payments	ACO
<ul style="list-style-type: none"> - Specific patients - Budget determined by hospital - Specific conditions - Specialist Focused - Organization keeps all savings - Payment from contracted org. - Less money (pilot project) - Up and Downside Risk 	<ul style="list-style-type: none"> - Every patient - Budget determined by CMS - All conditions - Primary Care Physician Focused - Savings shared with Medicare - Payments from Medicare - More money involved - Up and Downside Risk

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Bundled Payment for Care Improvement (BPCI) Models

	Model 1 (Concluded 12.31.2016)	Model 2	Model 3	Model 4
Episode	All DRGs; all acute patients	Selected DRGs; hospital plus post-acute period	Selected DRGs; post-acute period only	Selected DRGs; hospital plus readmissions
Services included in the bundle	All Part A services paid as part of the MS-DRG payment	All non-hospital Part A and B services during the initial inpatient stay, post-acute period and readmissions	All non-hospital Part A and B services during the post-acute period and readmissions	All non-hospital Part A and B services (including the hospital and physician) during initial inpatient stay and readmissions
Payment	Retrospective	Retrospective	Retrospective	Prospective
https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-13-2.html				
<div style="display: flex; justify-content: space-between;"> March 28, 2017 HCCA Compliance Institute 9 </div>				

**BPCI Model 2: September 2015 Annual Survey
Year 2 Evaluation**

- Majority of episode initiators were acute care hospitals.
- Medicare payments for hospitalization and 90 days post-discharge declined \$864 more for orthopedic surgery episodes at BPCI-participating hospitals than at non-participating hospitals because of reduced use of institutional post-acute care following hospitalization.
- Institutional post-acute care use declined for cardiovascular surgery episodes for BPCI.
- Participants indicated they tried to collaborate with area providers, especially post-acute care providers to improve care coordination and gain efficiency across an episode of care.
 - Participants indicated that it was challenging to establish relationships with other providers.
 - Patient education efforts were highlighted by participants, and may reported they focused on reducing post-acute care costs.

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**BPCI Model 3: September 2015 Annual Survey
Year 2 Evaluation**

- Skilled nursing facilities (SNFs) were the most dominate participants, followed by home health agencies (HHAs).
 - Only 1 inpatient rehab facility, long-term care hospital, and physician group practice participated.
- Standardized SNF payments and SNF days for SNF-initiated BPCI episodes declined relative to the comparison group across almost all episode groups.
 - Did not result in statistically significant declines in total episode payments.
- Quality was maintained or improved except in 3 isolated instances.
- Post-acute care providers formed or augmented existing relationships with other post-acute care providers and hospitals and engaged third-party administrators and data management contractors.
 - Noted challenges include difficulty forming relationships with hospitals and physicians affiliated with different provider systems.

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Comprehensive Care for Joint Replacement (CJR) Model

On November 16, 2015, CMS finalized regulations regarding the Comprehensive Care for Joint Replacement (CJR) Model

- Acute care hospitals in 67 MSAs are receiving retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity (LEJR).
 - MS-DRG 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities)
 - MS-DRG 470 (Major joint replacement or reattachment of lower extremity without major complications or comorbidities)
 - Separate episode target prices for MS-DRGs 469 and 470
- All related care (Part A and B) within 90 days of hospital discharge from the LEJR procedure are included in the episode of care, including hospital care, post acute care and hospital services, with certain exclusions.
- Began April 1, 2016.
- Repayment Risk: Y1 (0%) Y2 (5%) Y3 (10%) Y4-5 (20%)
- Gain Share Opportunity: Y1 (5%) Y2 (5%) Y3 (10%) Y4-5 (20%)

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Announced Episode-based Payment Initiatives

- December 20, 2016 – Final Rule
 - Effective February 18, 2017 – 42 CFR Part 512.
- Acute Myocardial Infarction (AMI) Model
 - Covers Part A and Part B items and services provided to acute care hospitals from initial hospitalization through 90 days after discharge in retrospective bundled payments
- Coronary Artery Bypass Graft (CABG) Model
 - Covers Part A and Part B items and services through retrospective bundled payments related to CABG treatment and recovery, from initial hospitalization through 90 days after discharge.
- Surgical Hip and Femur Fracture Treatment (SHFFT) Model
 - Covers Part A and Part B items and services through retrospective bundled payments related to SHFFT and recovery from hospitalization through 90 days after discharge.
- Performance Period: July 1, 2017 – June 30, 2021
- Participating hospitals coordinate care across providers and suppliers, including post-acute providers.

Purpose of the Anti-Kickback Statute

AKS designed to prevent improper referrals, which can lead to:



- Overutilization
- Increased costs
- Corruption of medical decision-making
- Patient steering
- Unfair competition

Anti-Kickback Statute Overview



Prohibits asking for or receiving anything of value to induce or reward referrals of Federal health care program business

Statutory Elements 42 U.S.C. 1320a-7b(b)

Anti-Kickback Statute prohibits:

- Knowingly and willfully
- Directly or indirectly offering, paying, soliciting, or receiving
- Remuneration
- In order to induce or reward the referral or purchase of (or arranging for the purchase of) items or services for which payment may be made by a Federal healthcare program

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Penalties for Kickbacks



Criminal fines up to \$25K; prison up to 5 years

Civil Money Penalty exposure, fines, program exclusion

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Exceptions and Safe Harbors


- Statutory exceptions (Congress) / regulatory safe harbors (OIG)
- Transactions satisfying *all* elements of Safe Harbor will not be prosecuted. Transactions *not* satisfying all elements are not *per se* illegal, but are subject to a facts-and-circumstances analysis

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Other Fraud and Abuse Laws: Stark	
Anti-Kickback Statute 42 USC 1320a-7b(b)	Physician Self-Referral Law (Stark) 42 USC 1395nn
Referrals from everyone	Referrals from a physician
Any items or services	Designated health services
Intent required (knowing and willful)	No intent standard for overpayment (strict liability) Intent required for civil monetary penalties for <i>knowing</i> violations
Criminal and civil penalties	Not criminal
Voluntary safe harbors (if not in safe harbor, may still be legal)	Mandatory exceptions (if not excepted, illegal)
OIG advisory opinion process http://www.oig.hhs.gov/compliance/advisory-opinions/index.asp	CMS advisory opinion process https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html
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Other Fraud and Abuse Laws: Beneficiary Inducement CMP	
Section 1128A(a)(5) of the Social Security Act provides that:	
<ul style="list-style-type: none"> any person who offers or transfers remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services 	
may be liable for civil money penalties of up to \$10,000 for each wrongful act.	
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Other Fraud and Abuse Laws: Beneficiary Inducement CMP - Exceptions	
<p>Certain exceptions, <i>e.g.</i>, Non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts; Incentives to promote the delivery of preventive care; reduction in the copayment amount for covered Outpatient Department Services; offer of items for free or less than FMV if unadvertised, and not tied to other services reimbursed under Medicare or Medicaid and individual has financial need.</p> <ul style="list-style-type: none"> Exceptions updated effective January 6, 2017. 	
<p>http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf</p>	
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Fraud and Abuse Waivers

- **Shared Savings Program Waivers** (Section 1899(f) of SSA)
 - Secretary may waive certain fraud and abuse laws **as necessary** to carry out the provisions of the Medicare Shared Savings Program.
 - October 29, 2015: OIG and CMS jointly published the Medicare Program; Final Waivers in Connection with the Shared Savings Program Final Rule.
- **Waivers for Innovation Center Models** (Section 1115A(d)(1) of SSA)
 - Secretary may waive certain fraud and abuse laws **as necessary** solely for purposes of testing payment and service delivery models developed by the Center for Medicare and Medicaid Innovation.
 - As of early January 2017: Six groups of waivers issued, including those for the BPCI models and CJR.

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Fraud and Abuse Waivers

- **Keep in Mind:** A waiver will apply to the arrangement(s) only if the individuals/entities seeking its protection are eligible to use the waiver and all conditions of the waiver are met.

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Fraud and Abuse Waivers v. Program Waivers

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>

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Waivers for BPCI Models

Sept. 13, 2012: OIG and CMS jointly issued waivers for specified arrangements involving BPCI Model 1 Participants.

- Waiver of the AKS and physician self-referral law in connection with:
 - Incentive payments – sharing of cost savings earned pursuant to CMS-approved gainsharing methodology and conditions set forth in Waiver Notice and Participation Agreement between the hospitals and CMS.

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Waivers for BPCI Models

July 26, 2013: OIG and CMS jointly issued waivers for specified arrangements involving BPCI Models 2, 3, and 4 Participants.

- Waiver of the AKS and physician self-referral law in connection with:
 - Savings Pool Contribution – Internal Cost Savings contributed by Episode-Integrated Providers (EIPs)
 - Incentive Payments – certain distributions from the BPCI Savings Pool
 - Gainsharing Payments – made by Gainsharer Group Practice to Gainsharer Group Practice Practitioners
- Waiver of the AKS and CMP prohibiting beneficiary inducements in connection with:
 - Patient engagement incentives – in-kind items or services provided by a Model Awardee, EIP, or Gainsharer to a Model Beneficiary

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Waivers for BPCI Models

- Waiver of AKS:
 - Professional Services Fee – for Model 4 only, payments from hospitals to physicians and non-physician practitioners for professional services furnished to hospital inpatients
- Each pursuant to conditions set forth in the applicable Waiver Notice and Participation Agreement

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Waivers for BPCI Models

- BPCI Model 1: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-1-Waivers.pdf>
- BPCI Model 2: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-2-Waivers.pdf>
- BPCI Model 3: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-3-Waivers.pdf>
- BPCI Model 4: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-4-Waivers.pdf>

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Waivers for CJR

- November 16, 2015: OIG and CMS jointly issued waivers for specified arrangements involving CJR Model participants.
- Waiver of the AKS and physician self-referral law in connection with:
 - Certain gainsharing and alignment payments between hospitals and providers or suppliers
 - Protects hospitals that share payments from CMS and hospital internal cost savings with other providers and suppliers.
 - Certain payments from a physician group practice ("PGP") to members of the physician practice
 - Protects arrangements in which a PGP that received a gainsharing payment from a hospital in the CJR model distributes a portion of those funds to its practice collaboration agents.
 - Each subject to certain conditions, including compliance with program rules.
 - Waiver of the AKS and CMP prohibiting beneficiary inducements in connection with:
 - Certain patient engagement incentives that promote preventive care or certain clinical goals
 - Allows participant hospitals to provide in-kind items and services to beneficiaries in CJR model episodes.
 - Incentives must comply with applicable program rules and waiver conditions.
- <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2015-CJR-Model-Waivers.pdf>

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The Limits of PAC Provider Collaboration

- Contracting and negotiating considerations
- HHA Collaboration Examples:
 - 3 OIG Advisory Opinions
 - 1 reported enforcement action

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The Limits of PAC Provider Collaboration		
<ul style="list-style-type: none"> ▪ 2006 Advisory Opinion 06-01 <ul style="list-style-type: none"> – Home Health Agency (“HHA”) provided pre-operative in-home and telephonic safety assessments by a licensed PT to patients without compensation. – OIG concluded situation presented grounds for imposition of a CMP and indicated there was an AKS risk. <ul style="list-style-type: none"> • Free preoperative in-home assessment constitutes remuneration beyond nominal value that induces patient business, in violation of Inducement to Beneficiary CMP Law • Telephonic home safety assessments may be of nominal value (\$10 or less) but OIG said there weren’t enough facts to establish this. 		
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The Limits of PAC Provider Collaboration		
<ul style="list-style-type: none"> ▪ 2007 Advisory Opinion 07-16 <ul style="list-style-type: none"> – HHA receives referral from surgeon when surgery scheduled; HHA makes one initial phone call to patient and reminds patient of referral and free choice. – HHA sends patient 2 educational videos of general application. <ul style="list-style-type: none"> • No patient specific information is provided. – OIG concluded it would not impose sanctions. <ul style="list-style-type: none"> • Videos furnished only after surgeon referral • Videos of general (not personalized) nature so useable by patient regardless of which HHA is ultimately selected. • Video unlikely to affect patient choice. • Video not provided by trained professional (such as a PT) so no personal relationship established. 		
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The Limits of PAC Provider Collaboration		
<ul style="list-style-type: none"> ▪ 2015 Advisory Opinion 15-12 <ul style="list-style-type: none"> – HHA first selected by patient in discharge planning process; HHA employee contacts patient by phone to inquire of desire for initial visit and patient selects whether visit is by phone or in person. Visit is to facilitate transition to home care service. At visit, HHA provides overview of home care experience, gives written materials and contact info and shares pictures of care team; no diagnostic or therapeutic service provided. 		
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The Limits of PAC Provider Collaboration		
<ul style="list-style-type: none">▪ 2015 Advisory Opinion 15-12 (cont.)<ul style="list-style-type: none">– OIG concluded intro visit is not remuneration to patient. No sanctions.<ul style="list-style-type: none">• Nature of visit reflected no actual or expected benefit to patient.• Only generalized information provided.• Purpose of visit to make for a smooth transition.• No diagnostic/therapeutic care provided.• Patient had already selected HHA.		
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The Limits of PAC Provider Collaboration		
<ul style="list-style-type: none">▪ 2016 OIG Enforcement Action<ul style="list-style-type: none">– HHA provided free discharge planning services to Hospital patients. HHA had no written contract with Hospital. Services were of a type typically provided by Hospital discharge planners. Hospital accepted free discharge planning services from HHA.– Hospital self reported to OIG and Government aggressively pursued Hospital.<ul style="list-style-type: none">• Hospital paid \$1.9 million.		
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The Limits of PAC Provider Collaboration		
<ul style="list-style-type: none">▪ Government pursued Hospital because:<ul style="list-style-type: none">– Potential steering violation – more than giving a list.– Alleged violation of AKS in that HHA gave free services to Hospital to obtain referrals for home care business.– Was outside of CJR and relaxed steerage prohibition in CJR; no application of CJR waiver<ul style="list-style-type: none">• Noted CJR Gainsharing Waiver precludes in-kind remuneration.		
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The Limits of PAC Provider Collaboration

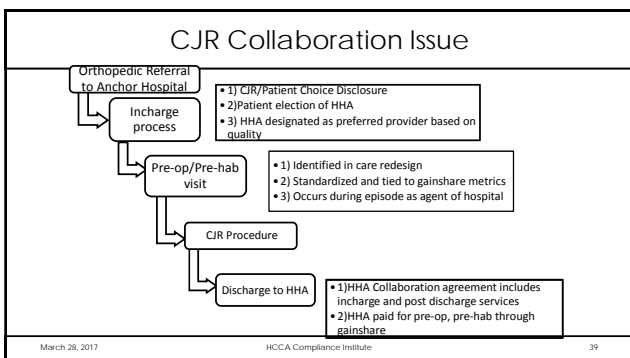
- OIG Advisory Opinions show progression of greater flexibility with key issues being (1) has HHA selection occurred before incentive (favorable); (2) is service more or less designed clinical relationship (if yes, unfavorable). Note – all 3 OIG AO's preceded the CJR/Bundled concepts.
- AKS enforcement matter raised steering issue and value of services to hospital without fmv compensation. Matter was outside of CJR with relaxed steering standard and potential CJR for some Gainsharing compensation.
- Challenges are to embrace new care redesign in CJR within the context of existing F&A Laws and develop arrangement that addresses various issues.
- 2 existing waivers in CJR have hurdles:
 - CMP waiver for beneficiary incentive requires HHA as agent; and incentive must occur during episode of care
 - Gainshare waiver covers payment not conduct.
- Concept has some risk but reach of CJR structure offers arguments.

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CJR Collaboration Issue

- Pre-operative Visit in Advance of CJR Episode
 - Invert discharge to intake with full patient choice.
 - Part of care redesign / Collaboration agreement between anchor hospital and HHA includes "Incharge".
 - Patient on intake participates in CJR care plan with required CJR disclosure.
 - Pre-op / Pre-hab visit physician authorized with full patient consent.
 - Gainsharing methodology rewards HHA on a global basis (i.e. not per prehab visit) but based upon a base fee for incharge services with a bonus based on quality (eg. Readmissions, which is a CMP waiver goal).

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CJR Collaboration Issue		
<ul style="list-style-type: none"> ▪ Issues – How can HHA be “agent” under CMP waiver and “HHA” for follow up? – Does early selection of HHA overcome issue of patient inducement? – Is Hospital paying fair market value for the assessment services through Gainsharing payment? – What if no home health on discharge? – Is “prehab” too clinical under prior AOs? – Better if: <ul style="list-style-type: none"> • HHA first contact to patient waits until hospitalization and HHA is selected by patient before it does assessment. • Hospital agrees to payment to HHA if no home care ordered (if home care ordered, there is potential Gainsharing but no FFS billing) 		
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“Bundling” Hypothetical		
<p>ABC Hospital System (“ABC”) is a large tertiary hospital system in Cleveland, Ohio. ABC has issued a request for proposal (“RFP”) to post-acute care providers to participate in a comprehensive post acute care bundling arrangement. ABC has stated in the RFP that it will not contract with every post acute care provider and is looking for one comprehensive post acute care solution for its proposed bundling arrangement. The RFP states that, among the criteria that ABC intends to use are quality of care, pricing, patient outcomes and rehospitalization rates. LTC, Inc. is a large post-acute care provider in the Cleveland, Ohio market. They own and operate nursing homes, home health agencies and hospices.</p>		
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“Bundling” Hypothetical		
<p>LTC, Inc. wants to win the RFP and is considering the following alternatives:</p> <ol style="list-style-type: none"> 1. LTC is willing to offer its nursing home services with a per diem pricing that represents a significant discount from LTC’s standard pricing. LTC is willing to offer a less significant discount on its home health services. The LTC nursing home services proposal, standing alone, will cause LTC to lose money. However, when combined with the home health services, LTC expects to break even or generate a small profit. 2. LTC is considering proposing a shared savings arrangement pursuant to which LTC will receive thirty percent (30%) of the savings generated from a selected baseline year and will also be obligated to pay thirty percent (30%) of the losses if the post acute care costs exceed the baseline year costs. 3. ABC acknowledges that the bundling arrangement cannot be optimized without dedicated patient navigators. However, ABC cannot afford to hire these navigators. LTC is considering offering to provide the navigators to ABC for free as part of the overall proposal. 		
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Swapping Overview



- "Swapping" – typically arrangements in which providers and/or suppliers give discounts on Medicare Part A services in exchange for referrals on Part D or Part B business
- Example: an LTC Pharmacy offers below market/discounted prices to SNF's on Part A drugs, which the SNF is responsible for paying for, in exchange for an agreement to provide access to higher paying reimbursable business on the SNF's Part D or B patients.

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Swapping Overview

• Red Flags to Look For:

- ♥ Rates below total costs of providing services suggest provider may swap these below-cost rates in exchange for separately billable, non-discounted Federal health care program business.
- ♥ Discounted prices to one buyer that are lower than the prices the provider offers to other buyers with similar volumes but no separately billable Federal health care program business.
- ♥ Discounts coupled with exclusive provider agreements or other agreements to refer Federal health care business.

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OIG Advisory Opinion 10-26

- Unfavorable
- Proposed payment plans for emergency and non-emergency transportation services provided for Medicaid-covered residents of skilled nursing facilities
- Additional guidance cited: reference to swapping discussions in 2003 Compliance Program Guidance (CPG) for Ambulance Suppliers and 2008 Supplemental CPG for Nursing Homes

Page 5 – OIG Advisory Opinion No. 10-26

offered to the SNF that are below the supplier's total costs of providing the services—in the facts presented here—give rise to an inference that the supplier and the SNF may be "swapping" the below-cost rates on business for which the SNF bears the business risk in exchange for other profitable non-discounted Federal business, from which the supplier can recoup losses incurred on the below-cost business, potentially through overutilization or abusive billing practices.

Based on the facts presented here, we are unable to exclude the possibility that the Requester may be offering improper discounts to the SNF's for their Medicaid Transport Services business with the intent to induce referrals of more lucrative Federal business. Nor are we able to exclude the possibility that the SNF's may be soliciting improper discounts on business for which they bear risk in exchange for referrals of business for which they bear no risk. Indeed, the Proposed Arrangement poses a substantial risk of such improper "swapping" of business that may run afoul of the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on Jansse reduced/under sections 1120(b)(7) or 1120A(a)(7) of the Act in those sections relate to the commission of acts described in section 1128B(1) of the Act in connection with the Proposed Arrangement. Any definitive conclusions regarding the existence of an anti-kickback violation requires a determination of

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OIG Advisory Opinion 12-09	
<ul style="list-style-type: none"> • Favorable • Reduced-rate arrangements for the provision of therapy services at state-operated veterans' homes • Additional guidance cited: footnote reference to 1999 and 2000 OIG letters on swapping arrangements - available on OIG website; see also ad ops 99-2 & 99-13 	<div style="font-size: small; margin-bottom: 10px;"> <p>¹ See, e.g., OIG Advisory Opinions 99-2, 99-13, and 10-26; OIG's September 22, 1999 letter on Discount Arrangements Between Clinical Labs and SNFs, and OIG's April 26, 2000 letter on Discount Arrangements Involving Ambulance Companies, Hospitals, and Skilled Nursing Facilities.</p> </div> <div style="font-size: x-small;"> <p>Page 6—OIG Advisory Opinion No. 12-09</p> <p>evaluating whether an improper nexus exists between the discounted business and referrals of Federal health care program business in a particular arrangement, we look for indicia that the discounted rate is not commercially reasonable in the absence of other, non-discounted business. For example, rates that are below a provider's total costs of providing services give rise to an inference that the provider may be swapping the below-cost rates on business for which the buyer bears the business risk in exchange for separately billable, non-discounted Federal health care program business. Another pricing arrangement that raises significant concerns is one that involves discounted prices to one buyer that are lower than the prices the provider offers to other buyers with similar volumes of business, but no potentially available separately billable Federal health care program business. Other suspect practices include, but are not limited to, discounts that are coupled with exclusive provider agreements and discounts or other pricing schemes (such as capitated arrangements) made in conjunction with explicit or implicit</p> </div>
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"Swapping" Hypothetical	
<p>ABC Rx is a long-term care institutional pharmacy. ABC Rx is growing rapidly and they badly want to enter into a long term contract with LTC, Inc., a large post-acute care provider. Currently, the LTC, Inc. nursing homes are paying for their Medicare Part A drugs at the state Medicaid allowable price. The LTC, Inc. nursing homes are also paying their current pharmacy for consulting pharmacists at \$30.00 per hour. ABC Rx offers to sell LTC, Inc. its Medicare Part A drugs at 95% of the state Medicaid allowable price and offers to provide consulting pharmacists at \$25.00 per hour. The ABC Rx offer is made with the expectation that ABC Rx will be the exclusive provider of institutional pharmacy services for all of the LTC, Inc. nursing homes, subject to patient choice, and would obtain all of the nursing homes' separately billable business, e.g., under Part B and Part D. At these rates, ABC Rx has a positive gross margin for the Medicare Part A drugs but ABC Rx pays its consulting pharmacists \$30.00 per hour. However, overall, ABC Rx would make a small profit on the arrangement, even if ABC Rx does not also become the exclusive provider of the nursing homes' separately billable business.</p>	
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What's Next?	
<ul style="list-style-type: none"> ▪ Repeal of ACA <ul style="list-style-type: none"> – Within hours of taking oath of office, President Trump signed an executive order "to seek the prompt repeal" of the ACA. <ul style="list-style-type: none"> • Directs Secretary of HHS to interpret the regulations loosely. – Rep. Tom Price, nominee for HHS Secretary believes bundled payment program is "experimenting with Americans' health." <ul style="list-style-type: none"> • Participation is mandatory before knowing how it will affect access to care. • Will issue more detailed interpretations of ACA based upon executive order once confirmed. – Will CMS Innovation Center, created by the ACA, disappear if/when ACA repealed or replaced? 	
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Conclusion



Questions?

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