Avera Health (IA, MN, NE, ND, SD)

Ascension Health (AL, AZ, AK, CT, DC, FL, ID, IL, IN KS, LA, MD, MI, MO, NY, OK, PA, TN, TX, WA, WI)

Carolinas HealthCare System (NC, SC)

Community Hospital Anderson (IN)

Erlanger Medical Center (TN)

Forrest General (MS)

Franciscan Missionaries of Our Lady Health System (LA)

Harris Health System (TX)

Hartford Hospital (CT)

Holy Name Medical Center (NJ)

Kaiser Permanente, Southern California Permanente Medical Group (CA)

Ohio Valley Health Services and Education Corporation (OH, WV)

Robert Wood Johnson University Hospital (NJ)

University of Pittsburgh Medical Center (PA)

September 8, 2015

Mr. Andrew M. Slavitt, MBA
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201
Attention: CMS–1631–P

Dear Mr. Slavitt,

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers who gathered to generate comments on the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 Proposed Rule (42 CFR Parts 405, 410, 411, 414, 425, 495), which was published in the *Federal Register* (Vol. 80, No. 135) on July 15, 2015.

The Provider Roundtable (PRT) includes representatives from 14 different health systems, serving patients in 33 states. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for services under Medicare, but do not have any specific financial relationship with vendors.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual policymaking process. We appreciate the opportunity to provide our comments to CMS. A full list of the current PRT members is provided in **Attachment A**.

Please feel free to contact me at 225-765-8847 or via email at: *Jen21306@ololrmc.com*.

Sincerely,

Jennifer L. Artigue, RHIT, CCS
PRT Chair and
Corporate Director, Health Information Management
Franciscan Missionaries of Our Lady Health System
5000 Hennessy Blvd.
Baton Rouge, LA 70808

Potentially Misvalued Services under the Physician Fee Schedule

The PRT appreciates that CMS's aim is to value all services appropriately under the Medicaid Physician Fee Schedule (MPFS) in order to reflect the relative resources utilized. For many years, CMS developed appropriate adjustments to the Relative Value Units (RVUs), taking into account recommendations provided by the American Medical Association's (AMA) Specialty Society Relative Value Scale Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and stakeholders. Section 1848(2) (k) (iii) of the Act authorized the Secretary of the Department of Health and Human Services to use other methods — such as surveys, data collection, or the use of analytic contractors to make recommendations regarding the adjustment of potentially misvalued codes.

In the CY 2016 MPFS Proposed Rule, CMS identified 118 potentially misvalued codes, which accounted for the majority of expenditures. In this list of potentially misvalued codes identified by CMS, 30 (about 25%) codes relate to radiology or radiation-oncology.

The PRT supports CMS's focus on categories of codes where there is a high risk of significant payment distortions, which narrows the list of codes to those more likely to be misvalued. If the codes are determined to be misvalued, they are likely to impact payments under the MPFS services due to the budget-neutral nature of the Fee Schedule.

Below is an excerpt from Table 45 on page 711: **CY 2016 MPFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty**

Specialty	Allowed Charged (mil)	Impact of Work of RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact
DIAGNOSTIC TESTING FACILITY	$719	0%	1%	0%	1%
INTERVENTIONAL RADIOLOGY	$296	0%	1%	0%	1%
NUCLEAR MEDICINE	$46	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	$103	0%	0%	0%	0%
RADIATION ONCOLOGY	$1,769	0%	-3%	0%	-3%
RADIATION THERAPY CENTERS	$52	0%	-9%	0%	-9%
RADIOLOGY	$4,472	0%	0%	0%	0%

The PRT recommends CMS to use the RUC process as they have in past, to provide an assessment and the validation of these services provided by the medical community are completed and available for review.

Improving the Valuation and Coding of the Global Package

The PRT appreciates CMS's goal to improve the validation of the various services included in surgical care. Under the global standard, payment rates are not updated to reflect the actual cost of care for post-surgical patients who receive follow-up care from providers other than the surgeon (e.g. primary care, etc.). If the follow-up evaluation and management (E&M) services are delivered by providers other than the surgeon, the global package surgery payments are likely to be too high, since beneficiaries do not typically receive the full number of follow-up services allotted for in the reimbursement for each surgical procedure code.

For this reason, the PRT agrees the valuation of E&M (i.e., RVUs) should be changed. The PRT supports Post-operative visits billed on an encounter basis, rather than being bundled with the surgery. We believe, however, that the surgical bundle should continue to include those components that are typically included (such as pre-operative work and the actual surgery).

Post-operative care can often include multiple providers. The PRT believes post-operative visits differ — both qualitatively and quantitatively — from other E&M services. We believe that the proposed 0-day package will facilitate greater transparency for the true cost and quality cost of services across heterogeneous care models.

We also believe that requiring beneficiary coinsurance for each follow-up service will create a financial burden for beneficiaries who have health issues that require multiple surgeries. There is a risk that a beneficiary may limit, or forego, medically reasonable and necessary care, which will result in higher incidences of post-operative infections and other adverse outcomes.

> **The PRT supports the use of new G-codes to identify surgeons' post-operative services versus primary care post-operative follow-up visits. We believe that this will enable CMS to gather appropriate data for future valuation of global services by multiple providers.**

<u>Advance Care Planning Services</u>

The PRT commends CMS for recognizing the long-standing efforts of physicians and NPPs who deliver advance care planning services to beneficiaries, and for providing reimbursement for these essential services. CMS proposes to re-assign CPT codes 99497 and 99498 (introduced by AMA in 2015) a status indicator of A for reimbursement effective January 01, 2016.

This proposal supports Medicare beneficiaries who wish to discuss options with their physician if they become too ill to make decisions, and provides the opportunity for the subsequent completion of an advance directive. This coverage and reimbursement will expand to other health care payors who follow Medicare guidelines, thus ensuring that *all* patient's wishes are respected, regardless of their insurance coverage.

The new proposal is an incentive for all health care providers to conduct these vital conversations in a compassionate and patient-centered way that respects the patient's dignity and

wishes. Advance care planning should be a collaborative effort between the beneficiary and her/his care team providers while one is able to affirm their wishes.

As studies have shown, one-quarter of Medicare spending is expended for health care provided during the patient's last year of life. CMS' proposal will help ensure that those resources are spent on treatment and intervention that align with the patient's wishes. Patients can decide whether they want to die at home or in the hospital, and under what circumstances (if any) they want life-sustaining treatment. Appropriate advance care planning will potentially decrease unnecessary resource use, because it will be very clear what the patient does and does not want.

We support CMS' proposed reimbursement for advance care planning services.

Target for Relative Value Adjustments for Misvalued Services

The PRT acknowledges under Section 220(d) of the Protecting Access to Medicare Act of 2014 (PAMA), CMS must establish an annual target for reductions in MPFS expenditures resulting from adjustments to relative values of misvalued codes.

For CY 2016, CMS proposes a methodology to implement a target adjustment of 0.5 percent of the estimated expenditures under the MPFS for each year from CY 2017 through CY 2020. Under CMS' proposal, if the net reductions in misvalued codes in CY 2016 are not equal to or greater than one percent of the estimated expenditures under the Fee Schedule, a reduction that is equal to the percentage difference between one percent and the estimated net reduction in expenditures resulting from misvalued code reductions must be made to all MPFS services.

CY 2016 represents a transition year for the process of proposing values for new, revised, and misvalued codes in the Proposed Rule rather than establishing them as interim final in the Final Rule with comment period. The net reduction is approximately 0.25 percent of the estimated amount of expenditures under the Fee Schedule for CY 2016.

The PRT agrees as CMS continues to transition to proposing values for targeted new, revised, and potentially misvalued codes, the impact of these interim final values in the final calculation will continue to diminish.

Misvalued Code Changes for Lower GI Endoscopy Services

The AMA's CPT Editorial Panel revised the lower GI endoscopy code set in CY 2015 following identification of certain codes as being potentially misvalued. The RUC provided recommendations for this valuation and, for CY 2016, CMS is proposing to implement the revised set of codes, including the revised values.

In CY 2015 CMS noted that changing practice patterns resulted in the use of separately reported anesthesia with these services. As a result, CMS is establishing a uniform approach to valuation for all services that include moderate sedation. CMS is also seeking recommendations from the RUC for the valuation of the work associated with moderate sedation alone before proposing an approach.

The PRT agrees with CMS' decision to address the provision of moderate sedation broadly, rather than on a code-by-code basis, using RUC survey data.

Other Areas

The PRT agrees the requirement to calculate "net" reductions should consider both the increases and the decreases to RVU for misvalued codes. By addressing "net" reductions, this limits the sensitivity surrounding CPT codes being added or deleted within a given section. Historically, the interim final values for misvalued codes have generally reflected reductions relative to original values across multiple years.

The PRT agrees with CMS' proposal to finalize values for a significant portion of misvalued codes and supports CMS' ability to make appropriate adjustments to values based on comments the agency receives. This will enable CMS to compare a target for any single year without regard to the overall changes taking place over three years.

Medicare Telehealth Services

The PRT fully supports CMS's proposal to add prolonged service inpatient CPT codes 99356 and 99357 to the approved Telehealth Services list. The prolonged services, while now on the approved list for Telehealth, are still subject to the limitations regarding visit frequency.

The PRT acknowledges the addition of four ESRD-related services 90963, 90964, 90965, and 90966. Even though these services are "for home dialysis," CMS recognizes the same services could also be furnished from an authorized originating site. The ESRD-related services will require a *"hands on"* clinical examination of the catheter access site, and must be furnished face-to-face by an approved provider (i.e., physician, certified nurse specialist [CNS], nurse practitioner [NP], or physician's assistant [PA]) during one of the two, three, or four monthly visits.

The PRT requests that CMS also add the *corresponding* four ESRD-related services 90967, 90968, 90969, and 90970 to the approved Medicare Telehealth Services list.

CMS continues to be cautious in response to the growing demand for expansion of telehealth services related to Critical Care/ICU Telemedicine; the agency claims that there is *"no evidence that the implementation of ICU TM significantly reduce[s] mortality rates or hospital length of stay."*

Critical Care services were previously submitted and rejected by CMS as a category 1 basis based on the fact that "no other like services with similarities" are on the current approved list. CMS then stated that critical care services would then need to be evaluated on the basis of a category 2 service (i.e., the services are not similar to the current list of approved telehealth services). CMS reviewed the American Telemedicine Association's (ATA) request, which cited several studies to support provision of these services on a category 2 basis. CMS concluded that there was no clinical benefit for the patient utilizing Telemedicine for Critical Care Services, and

that there was no evidence to support the use of telemedicine as a surrogate for face-to-face delivery of critical care services. CMS' statement that there is *"no evidence that the implementation of ICU TM significantly reduce[s] mortality rates or hospital length of stay"* was *not* a listed criteria for exclusion.

Telemedicine for Critical Care Services clearly meets the first three bullets in the Proposed Rule (page 41782 of the *Federal Register*) for the list of "examples of clinical benefit," which are:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.

The PRT believes that Telemedicine is safe and feasible for all patients. We further believe that advances in today's technology enable health care providers to deliver a focused, critical intervention no matter where the patient may be situated and/or what services are delivered.

For this reason, we respectfully request CMS to reconsider adding Critical Care Services provided via Telehealth.

The PRT salutes CMS' addition to amend §410.78 To Include Certified Registered Nurse Anesthetists as an authorized distant-site Practitioner for Telehealth Services. Acknowledging CRNAs as a practitioner under regulation §410.78(b)(2) further expands the ability to provide Telehealth Services.

"Incident to" Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

The PRT would like to take this opportunity to request clarification on CMS' proposals related to "Incident to" billing.

CMS proposes to clarify that the supervising physician's billing number should be used when submitting a claim for an "incident to" service that is provided by auxiliary personnel. So, if an NP, clinical nurse specialist, or PA provides an "incident to" service, the claim should be submitted under the billing number of the physician who is directly supervising that service.

In order to avoid confusion, CMS proposes to remove the last sentence from §410.26(b)(5), which currently states *"the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based*."

The PRT seeks to better understand CMS' intent in removing this language. Does CMS intend for a service that is initiated by one physician in a group practice be billed "incident to" when services related to the same course of treatment are provided by a mid-level provider but supervised by another physician in the same group practice?

In order to better illustrate our question, consider the following example: A new patient is seen by an oncologist who develops a course of treatment and plan of care for chemotherapy services provided to the patient over several weeks. During the course of treatment, an NP sees the patient in order to implement and monitor the treatment plan established by the oncologist. The oncologist directly supervises the services provided by the NP, and the claim is submitted using the oncologist's billing number. It is our understanding that this is an appropriate interpretation of the "incident to" provision.

Given the proposed language change, it is not clear if it is appropriate for the NP's service to be billed "incident to" in cases where the supervising physician is *not* the oncologist who provided the initial service and developed the plan of care, but is a different oncologist in the same group practice. Does this scenario continue to meet the requirements of "incident to" billing?

> **The PRT requests clarification about whether these scenarios meet the requirements of "incident to" billing.**

Other Provisions of the Proposed Regulations

Chronic Care Management (CCM) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Chronic care management (CCM) services include regular development and revision of a plan of care, communication with other treating health professionals, and medication management. The PRT applauds CMS' recognition of the extensive work necessary for primary care physicians and other practitioners (e.g., specialists) to plan to better manage beneficiaries' chronic care needs.

In CY 2015, CMS initiated payment for CCM for providers but excluded rural health clinics and Federally-Qualified Health Centers (FQHCs) from billing for CCM. The CY 2016 proposed expansion of CCM billing to these entities will expand Medicare beneficiaries' access to these primary care management services.

The CY 2016 MPFS Proposed Rule addresses the following three aspects of CCM services:

1. A payment rate of $41.92 for the code, which can be billed no more than once per month/qualified beneficiary.
2. Greater flexibility in the supervision of clinical staff providing CCM services.
3. A new requirement for standards for electronic health records.

The CY 2015 MPFS Final Rule amended the "incident to" regulation to require general supervision for CCM. This provision permits non-face-to-face care management services to be furnished through a centralized entity, as long as staff are properly supervised by a physician or non-physician practitioner. In the CY 2016 Proposed Rule, CMS requires that the billing physician or other practitioner must be the supervising physician or non-physician practitioner.

> **The PRT opposes this provision, which we believe will make it difficult for the physician to deliver CCM in a cost-effective manner.**

In the Proposed Rule, CMS proposes to compensate hospitals *only* if a patient has either been admitted to the hospital as an inpatient or has been a registered outpatient of the hospital within the last 12 months. In addition, the hospital would be required to have documentation of the patient's agreement to have CCM services provided in the patient's medical record. This agreement must include the beneficiary's decision to accept or decline the services, as well as an acknowledgement of monthly co-payments required by the beneficiary.

> **The PRT believes these requirements create an administrative burden to the provider and the current payment rate ($42.91) does not adequately reimburse providers for resources needed to meet the requirement.**

In the CY 2016 Proposed Rule, CMS states that only one hospital or clinical team will be paid for services in a given month. The limitation of one payment per month does not support the scope of services that beneficiaries who have CCM needs often have.

> **The PRT applauds CMS' recognition the need to provide a separate payment for collaborative care between a primary care physician and a specialist.**
>
> **The PRT recommends creation of a modifier to be appended to the specialist E&M and concert with the chronic disease diagnosis to establish a link between the primary care referral and the specialist for CCM.**

The PRT recognizes CMS' continued efforts to address beneficiaries' CCM needs. The inclusion of CCM for rural health clinics and FQHCs will help to facilitate comprehensive and coordinated primary care for beneficiaries.

Health Care Common Procedure Coding System (HCPCS) Coding for Rural Health Clinics (RHCs)

CMS is proposing to require *all* RHCs to begin reporting CPT/HCPCS codes for all services provided on and after January 01, 2016. These detailed data code sets are currently used by *all* other providers, including hospitals, physicians, NPPs, and FQHCs. The PRT believes that specifying the detailed data code sets' use will provide CMS with useful information on RHC's individual patient attributes and the types of services/procedures furnished by RHCs. RHCs will continue to be reimbursed the all-inclusive rate (AIR) with no change in payment methodology for encounters.

The proposal requires CPT/HCPCS codes to be reported along with, and in addition to, the standard Medicare revenue code site of service and associated charges for each service furnished.

Business office systems that generate claim forms can be easily modified to allow detailed billing of all services versus a summarization of services on the UF04 claim form for RHCs. Most procedures can be extrapolated from the electronic medical record (EMR) system. The operational challenges for providers will be capturing the appropriate charge for "all" services provided.

The PRT supports CMS' proposal to require "all" RHCs to begin reporting CPT/HCPCS codes for all services provided on and after January 01, 2016.

Physician Self-Referral Updates

The PRT appreciates CMS' proposals to update the physician self-referral regulations in order to better accommodate health care delivery and payment reform.

New Exception for Hospital Assistance to a Physician to Recruit a Nonphysician Practitioner to the Geographic Area Served by the Hospital

This proposed exception includes appropriate safeguards to prevent abuse, and includes a requirement that the nonphysician practitioner is a *bona fide* employee of the physician; that aggregate payments to the nonphysician practitioner, including benefits, be consistent with fair market value; and that the nonphysician practitioner has not practiced in the geographic area served by the hospital within the past three years.

In order to prevent program abuse, we believe that it is reasonable for there to be a limit on the number of times a hospital, FQHC, or RHC may assist the same physician or physician organization with the employment of a nonphysician practitioner. The limit of no more often than once every three years is reasonable and consistent with other physician self-referral regulations. We believe, however, that CMS should waive the frequency limit in the event the recruited non-physician practitioner remains employed by the physician, or physician organization, for less than one year.

In addition, in order to avoid confusion within the industry, CMS should make it clear the modified definition of "referral" as proposed for the new exception at 411.357(x) applies only to the exception for *Hospital Assistance to a Physician to Recruit a Nonphysician Practitioner to the Geographic Area Served by the Hospital* — and not to the physician self-referral regulations in their entirety. Misinterpretation of the proposed definition of referral at 411.357(x)(3) to be a change to the definition of referral at 411.351 — and therefore misconstrued to be applicable to the physician self-referral law in total — would be counter to CMS' intention to reduce provider burden and facilitate compliance. We encourage CMS to make this distinction clear in the Final Rule.

The PRT supports the creation of a new exception for Hospital Assistance to a Physician to Recruit a Nonphysician Practitioner to the Geographic Area Served by the Hospital.

We support the creation of a frequency limit but recommend that CMS waive the frequency limit in the event the recruited non-physician practitioner remains employed by the physician, or physician organization, for less than one year.

We strongly encourage CMS to clarify the use of the modified definition of "referral" is limited to this exception in order to minimize provider confusion.

Holdover Arrangements

The PRT supports CMS' proposal to permit indefinite holdovers for the exceptions for: (1) rental of office space; (2) rental of equipment; and (3) personal services arrangements as long as the arrangement complies with the applicable exception at the time it expires and continues to satisfy the terms of the exception during the holdover period.

> **We believe this change will reduce the burden encountered by both providers and CMS that results from a "technical" violation of the physician self-referral regulations related to an expired agreement when the arrangement otherwise continues to meet all other requirements of the applicable exception, and therefore poses no harm of program abuse.**

Remuneration

We appreciate CMS' comments in light of the Third Circuit's interpretation regarding "split bill" arrangements between physicians and DHS entities, and its opinion that such an arrangement is not remuneration between parties for purposes of the physician self-referral law.

> **We encourage CMS to propose regulatory revisions to address this issue either now or in the near future, in order to alleviate the continued confusion by providers, enforcement agencies, and the courts.**

We believe this guidance is urgently needed in order to prevent future enforcement actions against providers for "violations" not considered violations by CMS' own interpretation of the statute.

New Exception for Timeshare Arrangements

We appreciate CMS' proposal to create an exception for timeshare arrangements and encourage CMS to not limit the exception to rural and underserved areas. Such a restriction could prevent the otherwise appropriate use of the exception to protect needed timeshare arrangements in non-rural areas and areas not determined to be underserved, yet still experiencing a practical shortage in certain specialties or for other reasons that benefit patients of the community in the hospital's service area.

> **The PRT supports the proposal to create an exception for timeshare arrangements, but encourages CMS to not limit the exception to rural and underserved areas.**

Temporary Noncompliance with Signature Requirements

The PRT strongly supports CMS' proposal to modify the current regulations to allow parties 90 days to obtain required signatures for arrangements subject to the physician self-referral regulations, regardless of whether or not failure to obtain the signature(s) was inadvertent. We agree that temporary noncompliance with signature requirements does not pose a risk of program or patient abuse.

We encourage CMS to remove the requirement that this exception may not be used more often than once every three years with respect to the same physician. Given the rapidly changing health care environment — and the increased integration between physicians and hospitals required under new and evolving payment methodologies —hospitals are likely to need to enter into agreements with the same physician more often than in the past to respond to such changes.

The PRT does not believe that an otherwise compliant agreement poses risk to the program simply as the result of a late signature of one or more of the parties to the arrangement, even if the same physician is involved in more than one arrangement every three years.

> **We encourage CMS to adopt its proposal to allow parties 90 days to obtain required signatures, regardless of whether or not the failure to obtain the signature(s) was inadvertent. Further, we encourage CMS to remove the limitation that this exception can only be used once every three years with respect to the same physician.**

Changes in Health Care Delivery and Payment Systems since the Enactment of the Physician Self-Referral Law

We appreciate CMS' recognition of the barriers imposed by the physician self-referral regulations with regard to CMS' initiatives to align payment and quality under the Medicare program. CMS initiatives (such as Value Based Purchasing, the Medicare Shared Savings Program, and the proposed Comprehensive Care for Joint Replacement Payment Model [CCJR]) inherently require the collaboration and integration of DHS providers and referring physicians. Yet the physician self-referral law, by its design, and as recognized by CMS in the Proposed Rule, deliberately divides these parties.

We believe that the current exceptions to the physician self-referral regulations do not adequately support CMS' evolving payment and health care delivery systems. Even when CMS does provide allowances to promote integration (such as the ACO waivers, as published on November 2, 2011 in the *Federal Register*), the allowances are limited since these waivers *only* apply to ACOs participating or seeking to participate in the Shared Savings Program. This limitation significantly hinders the ability of hospitals that are not participating in an ACO to prepare for and adapt to changing payment models — which ultimately hinders CMS' goal of transforming its delivery and payments systems.

Hospitals that are working toward an increased level of integration with physicians in order to promote quality and cost savings, but are not yet ready to seek ACO status through the Shared Savings Program, are *not* protected by the waivers. As a result, providers must decide whether or not to enter into strategic arrangements with physicians to better prepare the facility to improve quality and adapt to evolving payment systems, even though such arrangements pose very real enforcement risk in today's regulatory environment. From a practical standpoint, hospitals must currently choose between limiting the risk of running afoul of the physician self-referral law or restructuring its arrangements with physicians in order to meet the challenges of existing and future Medicare payment models.

The PRT believes the physician self-referral law poses significant barriers to achieving clinical and financial integration. CMS' goals of improving quality of patient care while decreasing health care costs cannot be achieved without appropriate integration and collaboration between hospitals and physicians. Because DHS, under the physician self-referral law, includes *all* inpatient and outpatient services, virtually any agreement between physicians and hospitals poses significant risk, particularly in the current enforcement environment, absent any nefarious intent.

In addition, the application of specific waivers and allowances, integrated in a piecemeal fashion within various quality payment initiatives and programs, may actually strengthen rather than reduce barriers to the hospital-physician integration needed to promote CMS' evolving payment models. It does so by excluding hospitals that are not ready and/or eligible to participate. For those hospitals that *do* participate in specific initiatives, the complexity of the waivers, although designed to prevent the risk of program abuse, impose significant administrative burdens while requiring substantial and costly legal support. For example, the Participation Agreements proposed in the CCJR proposed rule require numerous complex operational, legal and accounting requirements that place virtually all compliance risk squarely on the shoulders of the participating hospital.

> **The PRT supports the creation of additional exceptions to promote current and future alternative payment models. In particular, the PRT asks CMS to consider establishing an exception for co-management agreements between hospitals and physicians.**

Co-management agreements improve the quality and cost effectiveness of particular service lines by engaging physicians to become active participants in the strategic planning, management, and quality initiatives of services provided in the hospital setting. Physicians are in a unique position to work with hospitals to accomplish these important goals. Yet, the physician self-referral regulations purposely and substantially hinder this collaboration.

The Office of Inspector General (OIG) published an advisory opinion (OIG Advisory Opinion No. 12-22) which describes certain safeguards that may be used to promote the integration of physicians and hospitals under co-management compensation models while reducing the risk of program or patient abuse. Such safeguards include:

1. The quality of patient care provided under the arrangement is monitored to protect against inappropriate reductions or limitations in patient care or services.
2. Cost savings measures do not restrict the availability of clinically appropriate devices and supplies.
3. Financial incentives related to cost savings components are reasonably limited in duration and amount and are subject to an annual cap which is set in advance.
4. The receipt of any part of the performance fee is <u>not</u> conditioned on the physician, or physician group:
    a. Stinting on patient care;
    b. Increasing referrals to the hospital;
    c. Cherry-picking healthy patients or those with desirable insurance; or
    d. Inappropriately accelerating patient discharges.

Hospitals that are not participants in an ACO (particularly community-based hospitals and smaller systems) need the ability to engage their independent physicians in adapting best practices to improve quality, efficiency and outcomes in the hospital setting. The personal services exception does not fully appreciate the structure of newer models of physician-hospital integration. Co-management agreements can be a more appropriate and achievable way for hospitals to integrate their physicians around quality of care goals without the significant investment needed for physician employment, practice acquisitions, and recruitment of new practitioners. We believe these types of agreements, when structured appropriately and in line with the OIG advisory opinion, pose a low risk of program abuse. For community based and smaller hospital systems, the ability to collaborate with physicians through a co-management arrangement to establish best practices and service value is a win for all parties, including the Medicare program and its beneficiaries.

As CMS considers the creation of additional physician-referral law exceptions, the PRT does not believe CMS should limit exceptions based on a hospital's performance on quality or value metrics. Although we recognize such exceptions would reward providers who have already demonstrated high performance on such metrics, it would hinder average or low-performing providers from entering into excepted physician compensation arrangements that have the potential to improve the quality performance of those providers, thereby improving the quality of care provided to Medicare beneficiaries.

The PRT strongly agrees there is a need for revision or clarification of the rules regarding indirect compensation arrangements and the exception at 411.357(p) for indirect compensation arrangements.

The physician self-referral rule states an indirect compensation arrangement exists if:

1. There is an unbroken chain of any number of persons or entities that have financial relationships between the referring physician and the DHS entity;
2. The referring physician receives *aggregate* compensation from the person or entity in the chain with which he has a direct financial arrangement that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the physician for the entity furnishing the DHS; and
3. The entity furnishing the DHS knows, or should know, the compensation, in the aggregate, varies with the volume or value of referrals.

Therefore, an indirect compensation arrangement exists only if the compensation received by the physician, in aggregate, varies with the volume or value of referrals to the DHS entity.

When a DHS provider determines an indirect compensation arrangement exists, the arrangement must be structured to meet the physician self-referral *Indirect Compensation Arrangement Exception*, which requires the compensation received by the referring physician not be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the DHS entity.

Therefore, the definition of indirect compensation looks at *aggregate* compensation while the exception looks to each individual payment. We believe the subtlety of this distinction causes confusion and inconsistent interpretation of the regulations. The PRT requests CMS to provide a series of examples of its interpretation and application of the definition of an indirect compensation arrangement and its interplay with the corresponding exception.

The PRT respectfully asks CMS to provide examples of its interpretation and application of the definition of an indirect compensation arrangement and the corresponding exception.

Attachment A: 2015 Provider Roundtable Members

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