The Academy Advisors

January 26, 2016

VIA ELECTIONIC MAIL & U.S. MAIL

The Honorable Orrin Hatch
Chairman, Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member, Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Johnny Isakson
United States Senator
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Mark Warner
United States Senator
Committee on Finance
United States Senate
Washington, DC 20510

RE: United States Committee on Finance, Bipartisan Chronic Care Working Group Policy Options Document

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson & Senator Warner:

We write to you under the banner of The Academy Advisors (The Advisors)[1], a policy coalition associated with The Health Management Academy[2], to provide feedback relating to the proposals set forth in the U.S. Senate Committee on Finance Chronic Care Working Group Policy Options Document. The Advisors' Leading Health Systems are providers of integrated care across the United States; composed of 14 health system partners that span over 28 states; 260 hospitals; and 2.5 million annual discharges. Our health system partners appreciate the opportunity to provide comments on your proposal and commend the Committee on its endeavor to address important chronic care issues.

We believe that the transition away from fee-for-service to coordinated care payment models will benefit all Medicare beneficiaries, particularly those with chronic conditions. Many of our health system partners are committed to leading the transformation of care delivery and are actively participating in numerous payment initiatives that reward value instead of volume. In 2014, The Advisors' health system partners provided care to over 390,000 Medicare beneficiaries through participation in the Pioneer and Medicare Shared Savings Program Accountable Care Organization (ACO) programs. As a result of clinical integration across the care continuum, our health system partners decreased total expenditures by $19.7 million with a higher than average quality score of 88.15 percent.

While we are supportive of many of the efforts being undertaken by the U.S. Senate Chronic Care Working Group (Chronic Care Working Group), our comments will focus on the following areas:[i]

1. The importance of developing a regulatory framework that allows enhanced care coordinated across the continuum of care.

2. Expanding innovation & technology, with a focus on telehealth and remote patient monitoring.

3. Providing flexibility for beneficiaries to participate in an accountable care organization (ACO).

4. Empowering individuals & caregivers in care delivery, specifically as it applies to eliminating barriers to care coordination under ACOs.

1.) Development Of A Regulatory Framework That Reduces Barriers To The Delivery Of Integrated Care And Allows Care Coordination For Patients With Chronic Conditions.

One of the primary goals of the Chronic Care Working Group is to develop policies that will increase care coordination among individual providers across care settings who are treating individuals living with chronic diseases.[ii] Enacting changes that increase care coordination requires the needs of the patient to be matched with the appropriate health care provider and/or service. When done effectively, care coordination results in more appropriate and less costly care, emphasizes prevention over treatment, and minimizes the fragmentation that often occurs in the provision of health care services. While enhanced care coordination is almost universally embraced as a desirable policy outcome, the current regulatory regime – designed to reduce fraud in a fee-for-service world – creates substantial barriers to the delivery of integrated care.

Since the enactment of the physician self-referral law in 1989 and the original enactment of the Anti-Kickback statute in 1972, the delivery of health care services and the payment for those services – among all payers, both government and private - has changed dramatically. By intent and design, the physician self-referral law separates entities that are furnishing designated health services (DHS) from physicians who are providing care to Medicare patients. Large integrated health systems, including those who constitute The Academy Advisors coalition, and other health care professionals face the challenge of trying to achieve system-wide clinical and financial integration to lower costs and improve health outcomes, while simultaneously complying with the physician self-referral, Anti-Kickback, and other laws and regulations that create care silos. <u>These care silos are even more impactful when dealing with non-acute conditions, such as those faced by patients with chronic conditions. While it is important that appropriate fraud & abuse protections remain intact for both beneficiary protection and program integrity, the current regime cannot remain without changes to accommodate innovative payment arrangements between health care providers that involve financial risk and include quality, outcomes, performance, care coordination and patient satisfaction metrics</u>.

The new payment models being deployed by Medicare, Medicaid and private commercial insurers are serving to change the interactions between physicians and other health care providers and stakeholders. Models such as ACOs reward health care providers for reducing the amount of care provided, as opposed to increasing it. Additionally, the Medicare Access and CHIP Reauthorization Act (MACRA) will further incentivize physicians to practice through coordinated care models, benefitting all patients, but particularly those with chronic conditions.

A constant theme across both the Chronic Care Working Group and the new payment models being implemented by the Centers for Medicare and Medicaid Services (CMS) is that health care providers must work together and coordinate closely to achieve the value and outcomes that new payment models demand. <u>New payment models, and the care coordination that occurs within them, is acutely important when it comes to managing the care of patients with chronic conditions</u>.

While the Affordable Care Act (ACA) legislated a pathway for regulatory waivers to be

developed and applied to its risk-based models, more should be done to encourage care coordination while still providing adequate program integrity.[iii] Further, no such legislative language creating a pathway for regulatory waivers was included in MACRA. [iv] As physicians and other eligible providers seek to provide care for patients with chronic conditions, regulatory accommodation will be necessary to create the proper alignment for health care providers to assume risk and deliver coordinated care.

We have attached as "Exhibit A" a copy of relevant parts of the comments submitted to CMS by The Academy Advisors in response to the Medicare Physician Fee Schedule Proposed Rule solicitation of feedback on ways to improve the regulatory regime to encourage care coordination and new payment models. Specifically, we included comments that address proposed regulatory accommodations for health care providers that enter into innovative payment models. We believe these comments are particularly relevant to the consideration of ways to enhance care coordination as it applies to patients with chronic conditions.

2.) Expanding Innovation & Technology, Specifically As It Pertains To Telehealth.

Improved care for patients with chronic conditions cannot be delivered without technological innovation. Leading Health Systems support the following policy proposals that encourage the use of technology to provide less costly, more efficient, high quality care:

- *Waiver of the geographic component of the originating site requirement for Medicare Shared Savings Program (MSSP) ACOs for both the two-sided models and the MSSP Track 1 ACO.*[v] A waiver of the geographic component will assist in ensuring that ACO beneficiaries receive consistent treatment and maximum care coordination under the ACO model. A waiver for the non-risk bearing MSSP Track 1 will help those ACOs build infrastructure and facilitate the transition toward assuming risk in the future.

- *Additional flexibility for MSSP ACOs to provide both social services and remote patient monitoring services that are not currently reimbursed by Medicare fee-for-service.*[vi] Remote patient monitoring has the potential to reduce future resource utilization, specifically as it applies to risk-bearing models. Social services are a key component of managing total population health, particularly for individuals afflicted with chronic conditions. Furthermore, the Committee should consider ways to incorporate remote patient monitoring into the new MACRA physician payment models.

3.) Providing Flexibility For Beneficiaries To Be Part Of An Accountable Care Organization.

Continued advancement in the area of beneficiary flexibility will be important to the success of the various Medicare ACO models. Leading Health Systems are supportive of:

- *Prospective beneficiary attribution for MSSP Track 1 ACOs*.[vii] Retrospective beneficiary attribution, while providing enhanced certainty for shared-saving calculations, fails to provide ACOs with the time and advance notice to best prepare for addressing the care of Medicare beneficiaries assigned to the respective ACO. All ACO models should receive prospective attribution or voluntary assignment moving forward.

- *Voluntary Assignment of ACO Beneficiaries*.[viii] Beneficiaries should have the option to voluntarily elect assignment to the ACO model in which their primary health care provider is participating. This voluntary election will allow beneficiaries to actively participate in their care, with a goal of higher engagement and improved outcomes.

- *Prospective ACO Payments.*[ix] Prospective beneficiary enrollment in an ACO, through either prospective assignment or voluntary enrollment, should also result in the option for an ACO to receive prospective upfront beneficiary payments. Many ACOs will find prospective payments to be very advantageous to engaging in appropriate care management, but at least initially, the upfront payment should be optional – at the discretion of the ACO - to allow a seamless transition toward partial or full capitation payments in the ACO model.

4.) Empowering Individuals & Caregivers in Care Delivery And Eliminating Barriers To Care Coordination Under Accountable Care Organizations (ACOs).

Improved care for patients with chronic conditions cannot be delivered without the elimination of barriers to care coordination. Specifically, Leading Health Systems are supportive of the following:

- *Allowing ACOs in two-sided risk models to waive beneficiary cost-sharing for items and services that treat a chronic condition.*[x] ACOs that are assuming risk for a population should be allowed discretion to determine the items and services for which cost-sharing would apply. Specifically, flexibility to waive copays, cost-sharing and deductibles should be afforded to ACOs for chronic care patients.

We appreciate the opportunity to provide comments to the U.S. Senate Chronic Care Working Group, and look forward to continuing the dialogue around ways to enhance care delivery for those afflicted with chronic conditions.

If you have any questions please do not hesitate to contact me at (703.647.1028) or Nathan@HMAcademy.com .

Yours sincerely,

The Academy Advisors

By: Nathaniel M. Bays, III
General Counsel & Executive Director

Exhibit A

Medicare Physician Fee Schedule Proposed Rule: Comments of The Academy Advisors on Regulatory Barriers to Integration, Reproduced in Part

Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be expected? What conditions should we place on such financial relationships to protect against program or patient abuse? Should a new exception be structured to protect services, rather than a specific type of financial relationship, when established conditions are met (similar to the in-office ancillary services exception)? Would legislative action be necessary to establish exceptions to support alternative payment models?

A new exception should be created – either by the Secretary or through legislation – to accommodate alternative payment models and innovative payment methodologies. If created through legislation, it would amend the exceptions for certain compensation arrangements in section 1877(e) to add a new exception for innovative payment methodologies that meet certain conditions to assure the promotion and advancement of accountability for quality, cost, coordination and overall care of patient populations. Under current law, the physician self-referral law prohibits even commercial payers from entering into arrangements with hospitals or between hospitals and their medical staffs intended to promote quality, cost, coordination and overall care of patient populations that in any way may take into account the value or volume of services to their own commercial patients.

In order to qualify for the exception, the arrangements would have to meet conditions that are already used to qualify ACOs and other risk sharing arrangements under the Stark and anti-kickback statutes. These safeguards include written agreements, transparency, and provider accountability, as well as prohibitions on double billing or shifting costs to federal health care payers.

The new exception would permit payers and providers to experiment with innovative non-fee-for-service payment methodologies that will encourage coordination of care, elimination of unnecessary and duplicative services, and enhanced patient satisfaction.

Is there a need for new exceptions to the physician self-referral law to support shared savings or "gainsharing" arrangements? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care? Would legislative action be necessary to establish exceptions to support shared savings or "gainsharing" arrangements?

There is a need for exceptions and/or flexibility to the physician self-referral law to support shared savings and gainsharing arrangements. The exception should be applicable between hospitals and physicians, without limitation. In order to qualify for the exception, the arrangements would have to meet conditions that are already used to qualify ACOs and other risk sharing arrangements under the Stark and anti-kickback statutes. These safeguards include written agreements, transparency, provider accountability, and quality/outcomes metrics, as well as

prohibitions on double billing or shifting costs to federal health care payers. Additionally, any gainsharing arrangement exception should ensure that all medically necessary care is provided, and that physicians are not able to share in savings if it is found that medically necessary care is not provided.

A regulatory exception for all hospital-physician relationships (including MSSPs) that provides hospitals and health systems an avenue to reimburse physicians based upon care coordination and reduced future utilization, simultaneously ensuring that all patients receive the highest quality care, will advance delivery reform and ensure program integrity and high-quality patient outcomes.

Should certain entities, such as those considered to provide high-value care to our beneficiaries, be permitted to compensate physicians in ways that other entities may not? For example, should we permit hospitals that meet established quality and value metrics under the Hospital VBP to pay bonus compensation from DHS revenues to physicians who help the hospital meet those metrics? If so, what conditions should we impose to protect against program and patient abuse? How should we define "high-value care" or "high-value entity"? Are there standards other than the value of the care provided to patients that would be appropriate as threshold standards for permitting a hospital or other entity furnishing DHS to compensate physicians in ways that other entities may not?

Entities that are committed to delivering value-based care should be permitted to compensate physicians in ways that other entities may not. Value-based care should be inclusive of current CMS delivery reform models, high performers in the Hospital VBP program, and other health care providers that are assuming risk for the health of their population (if not already included in one of the CMS delivery reform models). CMS, in considering the definition of "high-value care" and a "high-value entity" should account for the socio-economic status of populations. We support the ability of hospitals that meet established quality and value metrics under the Hospital VBP program to pay bonus compensation from DHS revenues to physicians who help the hospitals meet those metrics.

Given the changing incentives for health care providers under delivery system reform, should we deem certain compensation not to take into account the volume or value of referrals or other business generated by a physician? If so, what criteria should we impose for this deemed status to ensure that compensation paid to a physician is sufficiently attenuated from the volume or value of his referrals to or other business generated for the entity paying the compensation? Should we apply such a deeming provision only to certain types of entities furnishing DHS, such as hospitals that provide high value care to our beneficiaries?

As referenced earlier in our comments we believe the Secretary should consider the establishment of a safe harbor for compensation arrangements that are initially established at a fair market value rate which does not change during the term of the arrangement based on the value or volume of referrals (or other business generated where applicable.)

Under current law, there is confusion over whether a fair market value compensation arrangement complies with the Stark Law if the DHS entity anticipates that it will receive referrals or other business from the physician. While the regulations permit DHS providers to require employees and others to refer within networks subject to certain conditions, there is confusion in among the various judicial decisions and case law. The establishment of a safe harbor would provide certainty to health care providers. It would also be beneficial for health care providers that are providing care through alternative or innovative payment models.

By deeming certain compensation arrangements to not take into account the volume or value of referrals, it will be important for CMS to strike a balance between allowing such a deeming provision to be restricted to a high-performing cohort, but also not restricting the applicability to a group that is so small that it will impede or serve as a detriment to delivery reform activities within a specific geographic locale.

[1.] The Academy Advisors is the policy affiliate of The Health Management Academy, working with Leading Health Systems on policy analysis and development.

[2.] The Health Management Academy provides executive education and advisory services to C-suite executives from integrated health systems across the United States. Our health systems membership can be found at http://www.hmacademy.com

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[i] References to page numbers are from the U.S. Senate Committee on Finance Chronic Care Working Group Policy Options Document, published December 15, 2015.

[ii] *Id.* at Page 3

[iii] Patient Protection and Affordable Care Act, 42 U.S.C. §18001 (2010)

[iv] The Centers for Medicare and Medicaid Services, Office of the Actuary. *Estimated Financial Effects of the Medicare Access and CHIP Reauthorization Act of 2015 (H.R. 2).* April 9, 2015

[v] U.S. Senate Committee on Finance Chronic Care Working Group Policy Options Document, Page 17

[vi] *Id*. at Page 18

[vii] *Id.* at Page 21

[viii] *Id.*

[ix] *Id.*

[x] *Id.* at P. 25