UnityPoint Health
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

February 26, 2018

Patrice Drew
Office of Inspector General, Regulatory Affairs
Department of Health and Human Services
Attn: OIG-127-N
Room 5541C, Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

RE: OIG–127–N; Solicitation for developing new, and modifying existing, safe harbor provisions under the Federal Anti-Kickback Statute (§ 1128B(b) of the Social Security Act) as published in Vol. 82, No. 247 Federal Register 61229-61230 (Wednesday, December 27, 2017)

Submitted electronically via *http://www.regulations.gov*

Dear Ms. Drew:

UnityPoint Health ("UPH") appreciates the opportunity to provide comments on the OIG's annual solicitation of proposals and recommendations related to safe harbor provisions under the Anti-Kickback Statute. UPH is an integrated, nonprofit health system that provides care throughout Iowa, Illinois and Wisconsin. On an annual basis, UPH hospitals, clinics and home health agencies provide a full range of coordinated care to patients and families through more than 6.2 million patient visits. In addition, UPH is actively engaged in numerous initiatives which support population health and value-based care.

UPH is an early adopter of innovative value-based models and has partnered in Innovation Center demonstrations for seven years. UPH participates in Innovation Center contracts under the Bundled Payment for Care Improvement Model 2, the Home Health Value-Based Purchasing Model, and the Medicare Care Choices Model. In addition, UnityPoint Accountable Care (UAC) is the Accountable Care Organization (ACO) affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is the largest ACO participating in the Next Generation ACO Model with roughly 80,000 beneficiaries attributed to this program and has received first-year savings. Historically, UAC has providers that have

participated in the Medicare Shared Savings Program as well as providers from the Trinity Pioneer ACO, which was a rural ACO and achieved two years of savings.

Background: Since the initial 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. The Anti-Kickback Statute and its voluntary safe harbors need to keep pace with the Congressional and regulatory imperative to transition healthcare payment from a fee-for-service system to one of risk-based provider payment. Unless changes are established, providers will be discouraged from transitioning to risk arrangements, and thus disabling the savings to the Program intended by Congress. Recent developments in Part B reimbursement illustrate this point. Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed the Sustainable Growth Rate and replaced it with a framework (i.e. Quality Payment Program) that ties annual payment adjustments to quality performance. This framework encourages top tier performance through participation in Advanced Alternative Payment Models (AAPMs). As AAPMs are developed, there is no safe harbor provision that generally applies and therefore each model is subject to separate fraud and abuse waiver review. For an industry that is generally risk adverse, this creates further hesitation to innovate and move from volume to value payments. To promote further adoption of risk-bearing models, OIG should consider a new safe harbor provision for providers participating in innovative value-based payment models that establish networks to assume financial risk and provide high-value services.

Proposal: A new safe harbor provision for value-based arrangements by provider networks.

Value-based Payment Network Arrangements. (XX) As used in section 1128B of the Act, "remuneration" does not include any payment or exchange of anything of value paid or exchanged directly or indirectly between, among, or on behalf of one or more downstream providers or suppliers in or contracted with a network, as long as the following two standards are met –

(i) The network's governing body, who must have a fiduciary duty to the network pursuant to state law, including the duty of loyalty, acting consistently with that fiduciary duty, approve resolution(s):

(I) Make a bona fide determination that an arrangement or group of related arrangements is reasonably related to one or more of the network goals;

(II) Duly authorizing an arrangement(s) using the processes generally employed by the network's governing body; and

(III) Agreeing to promptly supply documentation demonstrating the network's compliance with (I) and (II) to the Secretary upon request;

(ii) The network governing body's bona fide determination with respect to an arrangement shall –

(I) Set the terms of each authorized arrangement in writing, including the items and services to be provided or exchanged;

(II) Set in advance the compensation to be paid or recouped or the value to be exchanged between and among the network, network providers and any contracted providers under each authorized arrangement; and

(III) Agree to require any downstream provider or supplier to comply with the requirements and conditions of the network's arrangements with the Centers for Medicare & Medicaid Services.

(iii) Definitions – For purposes of this exception, the following terms are defined as follows:

(I) "Downstream provider or supplier" shall refer to a provider or supplier in a network risk-sharing arrangement with a network or with another downstream provider.

(II) "Items and services" means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies, or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance.

(III) "Network" is defined as a public or private entity that is established, or organized and operated, by a downstream provider or supplier or group of downstream providers or suppliers to achieve one or more network goals through network risk-sharing arrangements. The network may have contractual arrangements with providers to provide services to individuals who are members or beneficiaries of health benefit plans the network has contracted with to provide services.

(IV) "Network goals" are defined as any of the following:

(aa) Promoting accountability for quality, cost, coordination, and overall care of patient populations, including patient populations that receive services from or through the network and which are reimbursed by government healthcare benefit programs;

(bb) Managing and coordinating care for patients through arrangements maintaining quality and cost and approved by the network and administered, furnished, or arranged for through providers in or contracted through the network; or

(cc) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including but not limited to Medicare beneficiaries, where efficient

service delivery includes, among other things, appropriate reduction of costs or growth in expenditures for health care items and services provided to patients, consistent with maintenance of quality of care standards, physician medical judgment, and patient freedom of choice.

(V) "Network risk-sharing arrangement" shall refer to one or more of the following mechanisms, which may be used in combination by a network to advance network goals –

(aa) An agreement to accept capitation payment for each patient.

(bb) An agreement to accept as payment a predetermined percentage of the network's revenue under the network substantial risk-sharing arrangement.

(cc) A network's use of significant financial incentives for downstream providers and suppliers in the network, with the aim of achieving utilization management and cost containment goals which include maintenance of utilization management and patient outcomes as established by the Secretary.

(VI) "Significant financial incentives" include the following:

(aa) Arrangements where downstream providers and suppliers in the network agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(1) To cover losses of the network due to network risk-sharing arrangement(s).

(2) To cover losses of other downstream providers and suppliers in the network due to network risk-sharing arrangement(s).

(3) To be returned to other downstream providers and suppliers if the network meets its utilization management, patient outcomes and cost containment goals for the specified time period on network risk-sharing arrangement(s).

(4) To be distributed among downstream providers and suppliers if the network meets its utilization management, patient outcomes and cost-containment goals for the specified time period on network risk-sharing arrangement(s).

(bb) Arrangements where downstream providers and suppliers agree to preestablished cost or utilization targets for the network and to subsequent significant financial rewards and penalties (which may include a reduction in payments to downstream providers and suppliers in the network) based on the network's performance in meeting the targets on network risk-sharing arrangement(s).

(cc) Other mechanisms that demonstrate significant shared financial risk on network risk-sharing arrangement(s).

We appreciate the opportunity to provide comments on the safe harbor provisions. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Government and External Affairs at Sabra.Rosener@unitypoint.org or 515-205-1206.

Sincerely,

Denny Drake
SVP, Corporate Integrity and General Counsel

Sabra Rosener
VP, Government and External Affairs