



# UnityPoint Health

Government & External Affairs  
1776 West Lakes Parkway, Suite 400  
West Des Moines, IA 50266  
[www.unitypoint.org](http://www.unitypoint.org)

December 31, 2019

Joanne M. Chiedi, Acting Inspector General  
Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-0936-AA10-P  
Room 5521, Cohen Building  
330 Independence Avenue SW  
Washington, DC 20201

RE: OIG-0936-AA10-P – Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements; published in Vol. 84, No. 201 Federal Register 55694-55765 on October 17, 2019.

*Submitted electronically via [www.regulations.gov](http://www.regulations.gov)*

Dear Acting Inspector General Chiedi:

UnityPoint Health (“UPH”) appreciates the opportunity to provide comments in response to the Office of Inspector General (OIG) proposed rule. Through more than 32,000 employees, our relationships with more than 310 physician clinics, 40 hospitals in metropolitan and rural communities and 17 home health locations throughout our 9 regions, UPH provides care throughout Iowa, western Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 7.9 million patient visits.

As an integrated healthcare system, UPH believes that patient-centered care is best supported by a value-based payment structure that enables healthcare providers to focus on population health instead of volume-based episodic care. UPH’s commitment to population health and value-based care is evidenced by our status as an early adopter of an Accountable Care Organization (ACO) framework. UnityPoint Health Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program as well as providers from the Pioneer ACO Model. UPH also has had regional participation in other Centers for Medicare and Medicaid Innovation (CMMI) Medicare models, including the Bundled Payments for Care Improvement (BPCI) Initiative, the Medicare Care Choices Model and the Rural Community Hospital Demonstration. Our home health agency, UnityPoint at Home, is licensed and practices in one of the nine states that is mandatorily participating in CMMI’s Home Health Value-Based Purchasing Model.

UnityPoint Health respectfully offers the following comments to the proposed regulatory framework.

## GENERAL PROVISIONS

*OIG is proposing to modify existing safe harbors to the anti-kickback statute and add new safe harbors and new CMP law exceptions to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes and efficiency.*

**Comment:** Although we have some specific comments on this proposed rule, **UnityPoint Health foremost appreciates the Administration’s continuing efforts to remove regulatory barriers to value-based healthcare service delivery.** UPH has long been an advocate for regulatory flexibilities to promote high quality care through value-based arrangements. Outdated fraud and abuse protections have presented some of the largest roadblocks to coordinated care. For years, UPH has attended various meetings, participated in calls and coalitions, and submitted formal comments on this vital issue, both inside and outside the rulemaking process. With the release of this proposed rule and the Centers for Medicare and Medicaid Services (CMS) proposal regarding modernizing and clarifying the physician self-referral law, we believe the Administration has heard us and the concerns of our providers and patients. We want to acknowledge these efforts and thank you. **We are confident that these rules are directionally correct, will positively impact healthcare delivery and be a hallmark of this Administration.**

## VALUE-BASED ARRANGEMENT SAFE HARBORS

*OIG is proposing to establish new hierarchical value-based arrangements safe harbors to the anti-kickback statute: full financial risk; substantial downside financial risk; and care coordination and management arrangements. Additionally, OIG is proposing a new safe harbor on patient engagement and support and revisions to personal services and management contracts and outcomes-based payment arrangements.*

**Comment:** UPH is an early adopter of value-based arrangements, including participating in several Medicare demonstrations. We firmly believe that this shift to value must occur in order to reduce the rise in healthcare costs and to help to provide more certainty to state and federal government budgets. **We applaud these supportive value-based care safe harbors and provision,** which will enable healthcare providers to continue to assume more risk and transition toward value-based payments.

**Definitions:** **UPH supports the proposed definitions,** despite differences from the CMS definitions for value-based arrangements. Generally, these definitions align with our prior comment letters and requests. We believe they nicely promote flexibility and encourage the numerous types of arrangements (healthcare services, physician alignment, network growth and integrated care delivery) that underscore the triple aim. **We are pleased that “value-based purpose” includes the fourth category of transitioning from volume to value for targeted populations.** In prior comment letters, we have stated the necessity of recognizing a goal/purpose of “encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including but not limited to Medicare beneficiaries.” As providers transition from volume to value, these infrastructure needs are weighty, cannot be understated and are foundational to achieving the first three value-based purposes: coordinating/managing care; improving quality; and appropriately reducing costs.

Coordination and Management of Care Purpose: While UPH supports this value-based purpose, it is interesting that OIG would select a single purpose as the lynchpin to be eligible for value-based arrangement safe harbors. This lynchpin requirement itself deflates the other value-based purposes and pigeon holes how providers must frame and develop value-based arrangements divergent from the physician self-referral law. **To avail the protections of the value-based arrangement safe harbors, we would request that OIG allow providers to select rather than mandate the value-based purpose(s) which is most appropriate for their target population.**

UPH is also alarmed that OIG is considering the preclusion of some or all protection under the proposed safe harbors for arrangements between entities that have common ownership. OIG is suggesting this as a method to “protect against fraudulent and abusive practices that parties attempt to characterize as the coordination and management of patient care.” **We would oppose these common ownership restrictions**, whether in the form of refinements to the value-based arrangement definition or added restrictions to the proposed safe harbors in paragraphs (ee), (ff), (gg), or (hh). First, we would point out that cycling of patients for financial gain runs contrary to value-based arrangements. We are unaware of value-based arrangements where such fraudulent and abusive practices exist, and OIG has provided no references for this assertion. Second, as an integrated health system, this would disallow safe harbor protections for physicians across care settings that are commonly trained and committed to standard, high-quality protocols and to unified care improvement and cost-containment efforts. We are mystified why OIG would want to deconstruct these efforts, especially in an industry that is already subject to heightened anti-trust regulations.

Value-Based Arrangements Safe Harbors: **UPH appreciates the hierarchical framework of proposed safe harbors and the greater regulatory flexibility that is bestowed upon agreements relative to their degree of risk-bearing.** This supports the notion that the value-based arrangements involving higher levels of downside risk curb fee-for-service incentives to order medically unnecessary or overly costly items and services. Overall, we believe these proposed safe harbors are intended to remove substantial barriers to intended reformation of the financial risk of healthcare delivery. Specific suggestions are below.

- **Full Financial Risk Safe Harbor. UPH agrees the full capitation arrangements (e.g. arrangements for cost of all patient care items and services) should be granted the upmost protection.** We appreciate that OIG permits a ramp-up period of 6 months to assume this level of risk. While we understand that risk-bearing is related to payor coverage, we would request that OIG consider explicitly stating the extent to which medication costs may be included. We would also suggest that OIG reconsider the scope of the qualifying arrangement. Instead of requiring a qualifying arrangement to be at risk for every service covered by the payor, the exception should target instead whether the arrangement has full financial risk for the items and services *to which the protected remuneration relates.*

In addition, OIG has limited these protections to first-tier arrangements, which would exclude agreements between VBE participants or with downstream participants. **UPH would request that**

**OIG consider a broader concept for provider arrangements included under this protection** – one that includes a value-based network with entities committed to advancing a value-based purpose. This would enable more care delivery flexibility. OIG has also added that value-based enterprises (VBE) are required to provide or arrange for both an operational utilization review program and quality assurance program. This requirement mirrors provisions modeled after Medicare section 1876 cost contract plans. These are fairly robust programs with associated hefty price tags for providers related to operations and compliance and require significant lead time for start-up. **We would request that OIG reconsider these robust operational requirements**, as VBEs are not the equivalent of managed care organizations.

- Substantial Downside Financial Risk Safe Harbor. UPH agrees with the inclusion of an intermediate safe harbor that includes shared loss or claw-back arrangements. Under this proposal, substantial downside financial risk is defined via four alternatives, as opposed to the single threshold in the physician self-referral proposal. The OIG thresholds vary depending upon the nature of the underlying repayment obligation or prospective payment. To provide consistency with Advanced Alternative Payment Model (AAPM) requirements, **we support aligning the definition of meaningful downside financial risk to the AAPM risk-bearing requirements**. This would allow OIG to align this safe harbor with current Congressional and regulatory value-based directives and to streamline policy direction and processes. This would also facilitate more uniform standards for providers and regulators and could be accomplished via a cross reference to the AAPM requirement to assure future alignment.

We would also echo our request for OIG to consider a broader concept for provider arrangements to include agreements between VBE participants as well as with downstream providers. Additionally, we would request further clarification in the form of regulatory text examples or future OIG guidance to indicate envisioned application, including permissible or impermissible bonus pools and gain-sharing arrangements under this safe harbor.

- Care Coordination Arrangements Safe Harbor. This safe harbor allows for the exchange of anything of value pursuant to a value-based arrangement, if all standards are met. As proposed, this safe harbor does not require the acceptance of significant risk, but does require greater agreement transparency and a more limited scope. **While UPH generally encourages promoting flexibility in arrangements that encourage provider engagement in innovation, we also believe that value-based safe harbors should be earned, tied to some level of risk-bearing and encourage physicians to aspire to take more risk**. That said, we support the proposed limitation in scope to in-kind, nonmonetary remuneration; the proposed mandated cost-sharing from value-based enterprise (VBE) participants; and a requirement for meaningful improvement and reporting related to performance or quality standards, including use of measures from the Quality Payment Program. We do believe that some proposed OIG requirements are overly prescriptive. For instance, the 60-day timeframe for termination upon a finding of that the value-based arrangement is unlikely to further care coordination and management or achieve evidence-based valid outcome measures is too prescriptive.

Patient Engagement Safe Harbor: UPH supports this new safe harbor targeting certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency. The outlined requirements resemble those for offering benefit enhancements within the Next Generation ACO. **We agree that tools and supports should be limited to the target population and support limiting this safe harbor to value-based enterprises involving risk-bearing arrangements.** As an experienced risk-bearing ACO entity, we can state that there is a learning curve in the appropriate use of benefit enhancements, and we believe that providers who are willing to bear risk should have a larger menu of tools to coordinate care and deliver services. In terms of program integrity concerns, risk-bearing providers would also be dissuaded from unnecessary or inappropriate use of such patient engagement tools.

Personal Services and Management Contracts Safe Harbor: This existing safe harbor is revised in response to the evolution of new payment models, such as shared savings, shared losses, episodic payments, gainsharing and pay-for-performance, and it is intended to add flexibility with respect to outcomes-based payments and part-time arrangements. Outcomes-based payments are linked to measurable patient care improvement or cost reduction to payors paired with maintained or improved patient care. The proposal excludes any payment that relates solely to the achievement of internal cost savings for the principal since potential savings would not accrue to the payor. This exclusion impacts a significant portion of healthcare delivery and would not protect arrangements for financial efficiencies related to the prospective payment systems for acute inpatient hospitals, home health agencies, hospice, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, or SNFs. **UPH would request that OIG reconsider this exclusion for internal cost savings, as this would be an effective means to promote efficient care in a fee-for-service setting and further test the appropriateness of relative value units (RVUs).**

#### **CMS-SPONSORED MODEL SAFE HARBOR**

*OIG is proposing to add a new safe harbor for certain remuneration provided in connection with a CMS-sponsored model, which should reduce the need for OIG to issue separate and distinct fraud and abuse waivers for new CMS-sponsored models.*

**Comment**: UPH applauds and supports this proposed safe harbor and, in prior comment letters, has specifically requested OIG consider a standardized process for AAPMs authorized via statute or through CMMI. As is currently the case when new AAPMs are released, there is standard language in requests for application that defers issuance of fraud and abuse waivers: *“For this model and consistent with the authority under section 1115A(d)(1), the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation.”* For an industry that is generally risk adverse, this has created further hesitation to innovate and move from volume to value payments. This safe harbor will enable CMMI to include advance notice of the applicability of fraud and abuse waivers for particular AAPMs.

#### **CYBERSECURITY TECHNOLOGY AND SERVICES AND EHR ITEMS AND SERVICES**

*OIG is proposing to add a new safe harbor for donations of cybersecurity technology and services as well*

*as revisions to the safe harbor for EHR items and services.*

**Comment:** Since 2016, UPH has been advocating for protection related to cybersecurity donations and we encourage its timely adoption with recommendations. As value-based arrangements and the requisite sharing of personal health information are increasing, the need to assure that data is not compromised has also increased. This safe harbor needs to be broad enough to cover changing technology and data sources. We would request OIG consider the following revision and clarification. First, **we would suggest that “technology” be defined to include hardware.** As proposed, this safe harbor is short-sighted and should include a more comprehensive definition of potential technology solutions for cybersecurity attacks. Furthermore, we believe that program integrity concerns are thwarted by the restriction that the technology or service is “used predominately to implement, maintain, or reestablish cybersecurity.” We would support a broad definition of hardware and do not agree that a risk assessment tool should be required at this point and in the absence of abuse. If hardware was to be included, we would oppose any finite percentage for recipient contributions or any cap on the value of donated hardware. Second, **we would recommend that the stand-alone safe harbor be clarified to state the object of the cybersecurity protection,** such as cybersecurity for electronic health records, medical devices, or other information technology that uses, captures, or maintains individually identifiable health information. The exception is silent as to the object of the cybersecurity protection and an explicit statement setting broad parameters would provide guidance and cover future technology advances.

**As for the existing safe harbor for electronic health records items and services, we value this safe harbor and agree that the sunset date of December 31, 2021 should be eliminated altogether rather than extended.** Additionally, UPH supports updates to language on interoperability and data lock-in, the clarification that donations of certain cybersecurity software and services are permitted, and the proposal to allow donations of replacement EHR technology. Lastly, we encourage OIG to consider reducing or eliminating the 15-percent contribution for all providers as this should be left up to market forces and the parties to negotiate.

## **PATIENT ARRANGEMENTS – OTHER PROTECTIONS**

*OIG is proposing several other protections for targeted programming to patients.*

**Comment:** We are generally supportive of the following protections with the addition of our recommendations.

Local Transportation Safe Harbor. This existing safe harbor for established patients and eligible entities is revised to slightly expand mileage limits for rural areas and for transportation for patients discharged from inpatient facilities. This would primarily impact hospitals and physician practices in rural areas that voluntarily transport patients to necessary medical appointments or to their homes following a hospital stay. As a healthcare provider with service areas spanning a large and often rural geographic area, **we wholeheartedly support the increase in the rural mileage from 50 to 75 miles.**

Medicare Shared Savings Program (MSSP) ACO Beneficiary Incentive Program Exception. In the

Bipartisan Budget Act (2018), two-sided ACOs participating in the MSSP were authorized to offer incentive payments to encourage assigned beneficiaries to obtain medically necessary primary care services. Under these policies, ACOs could apply to establish and operate a beneficiary incentive program to provide an incentive payment to each assigned beneficiary for each qualifying primary care service received. This exception codifies this statutory exception to the definition of “remuneration” related to the MSSP incentive program. **We would request that OIG consider expanding this exception to two-sided ACOs under the auspices of a CMMI demonstration.** Several ACO demonstrations have higher risk-bearing standards than this statutory requirement, which could serve as an eligibility floor for this exception.

Telehealth Technologies Civil Monetary Penalty (CMP) Exception. In response to the Bipartisan Budget Act (2018), this provision amends the definition of remuneration to create an exception to the prohibition on beneficiary inducements for telehealth technologies furnished to certain in-home dialysis patients. For this exception, telehealth technologies is defined as “*multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication . . . Telephones, facsimile machines, and electronic mail systems do not meet the definition of ‘telehealth technologies.’*” In the preamble, OIG further clarified that “*smart phones that allow for two-way, real-time interactive communication through secure, video conferencing applications would not be considered ‘telephones.’*” **UPH would recommend including real-time (synchronous) and store-and-forward (asynchronous) audio and video platforms.** While we agree that audio-only telephone interactions are not equivalent to interactions that are enhanced with video or other kinds of data transmission, we believe that providers can determine when the audio-only platform may be appropriate to assess whether the patient’s condition necessitates an office visit. We encourage OIG to not include a bright-line exclusion for asynchronous or audio-only telephone interactions.

Additional CMP Exceptions. The proposed safe harbor for patient engagement and support arrangements and the modifications to the local transportation safe harbor would also serve as exceptions to the beneficiary inducements CMP prohibition. **UPH is supportive of these exceptions** as described earlier in this comment letter.

#### **ALIGNMENT WITH CMS’S PHYSICIAN SELF-REFERRAL LAW PROPOSED RULE**

*In developing the proposed exceptions, definitions, and related policies, OIG has indicated that it coordinated closely with CMS. Where possible and feasible, OIG aligned with CMS’s proposals to ease the compliance burden on the regulated industry.*

**Comment: UPH acknowledges and appreciates OIG’s efforts to align the proposed anti-kickback statute and civil monetary penalty changes with the CMS’s physician self-referral law revisions. While we understand that there are different statutory underpinnings, we are concerned that these proposed rules are not in lockstep and will continue to create hesitation for providers considering value-based arrangements.** Differences include the divergent metrics for defining downside financial risk and the inconsistent inclusion of monetary remuneration under exceptions versus safe harbors. This will perpetuate an environment whereby there could be compliance under the physician self-referral law but a violation under the anti-kickback statute. Although we understand the OIG serves as a

backstop and enforces a criminal statute, we would still encourage further alignment between these two regulations and urge both OIG and CMS to actively involve stakeholders in these discussions aimed at further refinements.

UPH is pleased to provide comments to the proposed OIG regulations and their impact on our integrated healthcare system. We have also submitted separate and distinct comments related to the companion CMS-1720-P; Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government and External Affairs at [sabra.rosener@unitypoint.org](mailto:sabra.rosener@unitypoint.org) or 515-205-1206.

Sincerely,



Dennis Drake, JD  
SVP, Corporate Integrity and General Counsel



Sabra Rosener, JD  
VP, Government & External Affairs