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December 31, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–1720–P
P.O. Box 8013
Baltimore, MD 21244–1850

RE: CMS–1720–P; Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations; published in Vol, 84, No. 201 Federal Register 55766-55847 on October 17, 2019.

Submitted electronically via www.regulations.gov

Dear Administrator Verma:

UnityPoint Health ("UPH") appreciates the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed rule to establish exceptions to the physician self-referral law and provides guidance for physicians and healthcare providers and suppliers whose financial relationships are governed by this law. 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 rule.

GENERAL PROVISIONS

CMS is proposing to alleviate the undue impact of the physician self-referral statute and regulations on parties that participate in alternative payment models and other novel financial arrangements and to facilitate care coordination among such parties. Key features also include the creation of two other exceptions for certain arrangements under which a physician receives limited remuneration and for donations of cybersecurity technology and related services and a revision to the exception for electronic health records (EHR) items and services.

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 Office of the Inspector General's (OIG) proposal regarding anti-kickback statute safe harbors and civil monetary penalty rules for beneficiary inducements, 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 will positively impact healthcare delivery and be a hallmark of this Administration**.

TRANSITION TO VALUE-BASED CARE DELIVERY AND PAYMENT

CMS is proposing three new hierarchical value-based care exceptions: full risk arrangements, value-based arrangements with meaningful downside financial risk, and value-based arrangements. These new exceptions for value-based arrangements would also be applicable to indirect compensation arrangements. In addition, CMS is proposing revisions to the group practice rules related to the distribution of profits directly attributable to a physician's participation in a value-based enterprise.

Comment: UPH is an early adopter of value-based arrangements and has partnered with CMS in several innovation 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 new value-based care exceptions**, which will enable healthcare providers to continue to assume more risk and transition toward value-based payments. These exceptions emphasize care delivery innovation and afford physician self-referral law flexibility for parties to enter into risk-bearing arrangements. Within these exceptions, we want to acknowledge that CMS has refrained from including volume-based, fee-for-service terminology (such as fair market value, commercial reasonableness, and "volume or value of referrals" standards), as such terms are ill-suited and misdirected within value-based arrangements.

Definitions**: UPH supports the proposed definitions**. These align with our prior comment letters and requests. In general, we believe that these definitions nicely promote flexibility and encourage the numerous types of healthcare delivery options (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.

Exceptions: **UPH appreciates the proposed hierarchical framework of exceptions for value-based arrangements and the greater regulatory flexibility that is bestowed upon agreements relative to their degree of risk-bearing**. This supports the notion that the risks of overutilization, which the physician self-referral law is intended to prevent, do not apply to payment arrangements that pay for patient outcomes. We believe that the economic incentive to overutilize healthcare services does not necessarily exist in these arrangements, and these proposed exceptions are intended to remove a substantial barrier to the intended reformation of the financial risk of healthcare delivery. Specific suggestions are below.

- *Full Financial Risk Exception*. **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 CMS 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 CMS consider explicitly stating the extent to which medication costs may be included. In addition, we would suggest that CMS 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 instead target whether the arrangement has full financial risk for the items and services *to which the protected remuneration relates*.

- *Meaningful Financial Risk Exception*. **UPH agrees with the inclusion of an intermediate exception that would include shared loss or claw-back arrangements.** Under this proposal, meaningful downside financial risk is defined to be no less than 25 percent of the remuneration value. While we are generally supportive of this approach, we are less resolute as to the 25-percent threshold. Our hesitation appears to be affirmed by the OIG proposal for value-based arrangements with substantial downside financial risk, which authorizes four different thresholds. **To provide consistency with Advanced Alternative Payment Model (AAPM) requirements, CMS could consider aligning the definition of meaningful downside financial risk for physician self-referral law to the AAPM risk-bearing requirements.** While we agree with CMS that the "physician self-referral law policy is not the appropriate place to define or identify alternative payment models . . . [and the focus of this proposal is] to remove the regulatory barriers that inhibit the transformation to value-based care," we believe that CMS should attempt to align this regulatory requirement with current Congressional and regulatory value-based directives. We do not view consistency with Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and AAPM structure as defining or identifying payment models, but rather harmonizing these provisions to streamline policy direction and processes. This would facilitate more uniform standards for providers and regulators and could be accomplished via a cross reference to the AAPM requirement to assure future alignment.

- *Value-Based Arrangements Exception.* This option is a participation onramp to value-based payment models. As proposed, this exception does not require the acceptance of significant risk, but does require greater agreement transparency. **While UPH generally encourages promoting flexibility in arrangements that encourage provider engagement in innovation, we also believe that value-based exceptions should be earned, tied to some level of risk-bearing and encourage physicians to aspire to take more risk.** That said, we would support alternative approaches that limit exceptions to in-kind, nonmonetary remuneration; mandate cost-sharing from value-based enterprise (VBE) participants; or are based on meaningful improvement related to performance or quality standards. We do not necessarily support the prescriptiveness of the CMS alternatives within the proposed rule. For instance, the timeframe for recipient contributions of 15 percent seems arbitrary and likely to result in self-disclosure costs that outweigh its benefit.

  In the value-based arrangements preamble, CMS provides lengthy discussion related to monitoring requirements of value-based activities in furtherance of value-based purposes. We fully support the concept and practice of monitoring compliance with value-based arrangements. While we understand the need for program integrity, we are concerned that the comments being sought on monitoring scope may have chilled any desire for providers to use this exception. **We would encourage CMS to clearly include any monitoring or oversight duties specifically within the final rule and allow additional comment period for stakeholder feedback.**

Harmonizing Provisions: **UPH supports specific language recognizing VBE participation in the context of indirect compensation arrangements as well as profit distribution for physicians within group practices**. In the absence of specific language, the regulatory landscape is unclear. Of the three alternatives proposed to recognize indirect value-based arrangements, we would prefer the option that applies proposed exceptions to value-based arrangements (proposed in 411.354(d)(4)(ii)). The proposed group practice revision clarifies that profits distributed to participating physicians are not deemed to directly take into account the volume or value of the physician's referrals. This reflects how ACO or other value-based arrangements commonly handle funds flow agreements, and how group practices operationalize the distribution of funds directly to their participating physicians.

FUNDAMENTAL TERMINOLOGY AND REQUIREMENTS

CMS is proposing to clarify the terms "commercially reasonable" and "fair market value" as well as the standard for taking into account volume or value of referrals.

Comment: The interpretation of these terms and standard has been the subject of ongoing uncertainty with the practical result being that providers have foregone many beneficial arrangements aimed at healthcare value and outcomes. While these changes are significant and to be celebrated, it is worth noting that they only apply in the context of CMS and the physician self-referral law and do not cross over to the anti-kickback statute and OIG, the Department of Justice or the Internal Revenue Service.

- *Commercial reasonableness*. **While UPH supports the definition as proposed, the language related to consideration of profitability could be strengthened,** and we would encourage CMS to consider

substituting the second sentence with the following: "Commercial reasonableness is unrelated to the profitability of the arrangement to one or more of the parties."

- *Fair market value*. **UPH supports the definition as proposed.** We appreciate the definition being restructured to separate fair market value from general market value and that, within those definitions, general value is distinguished from the value of equipment rental and office space rental. Most important is that CMS has revised the definition of fair market value to eliminate the connection to the volume or value standard (e.g. whether compensation takes into account or anticipates referrals).

- *Takes into account volume or value of referrals*. **UPH supports the proposed standard**. We would request that CMS resolve outstanding issues about the use of personal productivity compensation and the volume or value standard. Specifically, we request that CMS make clear in regulatory text that compensation for personal productivity is permissible under the personal services, fair market value compensation and indirect compensation arrangements exceptions.

CYBERSECURITY AND EHR DONATIONS

CMS is proposing to permit donations of cybersecurity technology via a new stand-alone exception and a revision to the existing provision on electronic health records (EHR) renumeration. The EHR exception is also modified to reference information blocking as defined in statute.

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 exception needs to be broad enough to cover changing technology and data sources. With that in mind, we would request that CMS consider the following revision and clarification. First, **we would suggest that "technology" be defined to include hardware**. We believe this exclusion 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 subsection (bb)(1) 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 EHR exception, we value this exception 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 CMS 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.

PROVIDING FLEXIBILITY FOR NONABUSIVE BUSINESS PRACTICES

CMS is proposing a new exception for situations involving limited renumeration to a physician and a special rule to permit parties to execute written agreements within 90 days. CMS is also proposing to redefine "designated health services" to exclude certain inpatient services.

Comment: This proposed rule recognizes other operational issues appropriately characterized as nonabusive. **UPH supports both the "limited remuneration to a physician" exception for annual payments under $3,500 and the rule permitting writings to be executed within 90 days of when an arrangement begins**. These will reduce the sheer number of self-disclosures and enable providers and CMS to divert resources to other areas.

The rule also revises the definition of ''designated health services'' (DHS) to clarify that a service provided by a hospital to an inpatient does not constitute a DHS payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). UPH had previous requested that the definition of "referral" be revised to address this for any category of DHS. **While we support this DHS revision, we do believe that CMS should extend this proposal to analogous services provided by hospitals that are not paid under the IPPS (such as Critical Access Hospitals) as well as to outpatient hospital services.** We do not find it compelling that outpatient services should be excluded because referrals are not as common. When additional payments or an increase in payment are not at issue, the physician self-referral law should be applied universally, regardless of setting.

PRICE TRANSPARENCY

CMS is seeking comments on how to pursue price transparency objectives in the context of the physician self-referral law, both in the context of a value-based healthcare system and otherwise, and how to overcome the technical, operational, legal, cultural, and other challenges to including price transparency requirements in the physician self-referral law.

Comment: When choosing healthcare providers, consumers consider a number of factors in their value equation, including location, experience, services, quality, outcomes and cost. **UPH is committed to meaningful price transparency for consumers**. Our price transparency focus is on providing each patient or prospective patient personalized information for them to understand their benefit plans and their out-of-pocket responsibility, enabling them to be educated consumers. **We do not believe that the inclusion of a price transparency requirement in a value-based exception would provide additional protections against program or patient fraud or abuse. While we support the availability of pricing information and out-of-pocket costs to patients, we do not believe that healthcare providers are the best source of pricing information for many consumers.** Out-of-pocket costs are most readily available from a consumer's insurer or health plan and may be obtained by contacting the health plan directly. As opposed to a healthcare provider, the third-party health plan will have access to the

consumer's contract rates and specific benefits, such as deductibles, co-pays or co-insurances. The health plan also has the ability to give the consumer the full out-of-pocket costs that would include the hospital, physician and any other normal services for the episode of care as well as the ability to compare across all providers. Health plans currently provide cost/liability information in a pre-authorization process as well as in an explanation of benefits document.

ALIGNMENT WITH OIG'S PROPOSED ANTI-KICKBACK STATUTE SAFE HARBOR PROPOSED RULE

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

Comment: **UPH acknowledges and appreciates CMS's efforts to align the proposed physician self-referral law changes with the OIG's revisions to the anti-kickback statute and civil monetary penalty regulations. 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 renumeration 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. We would encourage further alignment between these two regulations and urge both CMS and OIG to actively involve stakeholders in these discussions aimed at further refinements.

UPH is pleased to provide comments to the proposed CMS regulations and their impact on our integrated healthcare system. This proposal is a significant effort to remove regulatory barriers in pursuit of value-based care and arrangements. We have also submitted separate and distinct comments related to the companion 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. 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 or 515-205-1206.

Sincerely,

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