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ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

September 11, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"

On **Thursday, September 13, 2018, at 1:15 pm., in Room 2322 of the Rayburn House Office Building**, the Subcommittee on Health will hold a hearing titled "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare."

I. CURRENT ISSUES IN VALUE-BASED CARE IN FEE-FOR-SERVICE MEDICARE

A. Accountable Care Organizations

The Affordable Care Act established new models for delivering healthcare, including Accountable Care Organizations (ACOs), to encourage health care providers to better coordinate patient care. An ACO is a group of providers who work together to improve the coordination, quality, and efficiency of care provided to beneficiaries. The Medicare program shares a portion of savings with those ACOs that achieve target savings and meet quality performance standards. The Centers for Medicare & Medicaid Services (CMS) supports a number of different types of ACOs, starting with Track 1 ACOs (which include no downside financial risk) through the Next Generation ACO model with the greatest risk (up to 100 percent downside financial risk and a 100 percent shared savings rate).

Today, there are 472 ACOs operating in the United States, caring for 9 million beneficiaries. The first six years of the ACO program have proven that incentivizing better care through shared savings does lead to Medicare savings and better care for beneficiaries. ACOs

saved Medicare an estimated $1.1 billion in 2017, with net savings of $314 million after bonuses were paid out.[1] This is a significant improvement over savings in past years.

Studies have also shown that ACOs reduced readmissions from skilled nursing facilities, generated fewer emergency department visits and hospitalizations, and had overall less Medicare spending relative to comparison groups.[2] Additionally, the experience with the Shared Savings Program has shown that ACOs tend to do better over time, both in terms of performance on quality measures and at generating savings, as they gain experience with care transformation.[3] ACOs reported that success under the Next Generation ACO model required significant investments in care management staff, health information technology, and data collection, processing, and analytics.[4]

Despite the growing track record of improving ACO quality and ACO-related Medicare savings, CMS proposed in a rule on August 17, to shorten the glide path for new ACOs to assume financial risk, by reducing the maximum time in an upside-only model from the current six years, to two years.[5] That proposal, coupled with CMS's proposal to cut shared savings in half—from 50 percent to 25 percent for Track 1 ACOs—could deter new entrants to the ACO program.

B. The Stark Self-Referral Law

The "Stark" physician self-referral law is meant to prevent providers' financial interests from interfering with clinical decisions that can lead to overutilization of health care services or care that may not be in the best interests of patients. Financial incentives could lead, for example, to the referral of patients to lower quality services, or potentially subject patients to unnecessary testing.

The Stark law prohibits physicians from referring Medicare beneficiaries to facilities in which they (or a close family member) have a financial stake (such as an ownership, investment interest, or compensation arrangement) by barring that facility from billing for Medicare services

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[1] *Medicare ACOs saved $1.1B in 2017, CMS data show*, Healthcare Dive (Sept. 4, 2018).

[2] Centers for Medicare & Medicaid Services, *Proposed Rule: Medicare; Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success*, 83 FR 41786 (Aug. 17, 2018).

[3] Chris Dawe and Nico Lewine, *Five Simple Charts Show That Risk-Based ACOs Are Working*, Health Affairs (Dec. 13, 2017) (www.healthaffairs.org/do/10.1377/hblog20171212.585293/full/).

[4] NORC, *First Annual Report: Next Generation Accountable Care Organization Model Evaluation* (Aug. 27, 2018) (https://innovation.cms.gov/Files/reports/nextgenaco-firstannrpt.pdf).

[5] Centers for Medicare & Medicaid Services, *Proposed Rule: Medicare; Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success*, 83 FR 41786 (Aug. 17, 2018).

performed as a result of such a referral. Violations of the Stark law are punishable through civil monetary penalties and exclusion from federal health care programs, like Medicare and Medicaid. The Stark law is a strict liability statute, which does not necessitate an intent to violate the law. Any breach of the law, whether intended or not, may subject the violator to penalties, regardless of the nature of the violation.

The Stark law includes exceptions for certain ownership/investment and compensation arrangements, and certain other services, such as in-office, ancillary services (e.g. imaging and lab tests), *bona fide* employment arrangements, and fair market value arrangements. Research conducted by the Medicare Payment Advisory Commission (MedPAC) and other organizations has shown that overutilization may occur in services meeting these exemptions. In June 2011, MedPAC cited evidence that physicians self-referring imaging tests led to increased imaging utilization and resource use compared to patient care episodes in which the physician did not self-refer imaging.[6] Similarly, multiple GAO reports have found that self-referrals in advanced diagnostic imaging, anatomic pathology, radiation oncology, and physical therapy lead to increased utilization and excessive costs.[7]

Some providers argue that the Stark law prevents them from coordinating care and disincentivizes them from entering into innovative alternative payment models and arrangements. For example, the Stark law may prevent a physician practice or hospital from utilizing revenue from designated health services to financially reward or penalize physicians for adherence or deviation from clinical best practices, because compensation cannot turn on the "volume or value" of referrals or other business generated by the referring physician.[8]

CMS has authority to create exceptions to Stark and could create a new exception for certain types of value-based payment arrangements. CMS also has broad authority to waive the Stark law for accountable care organizations (ACOs) and for all Innovation Center models. Stakeholders may also seek a written advisory opinion from CMS on whether a particular referral arrangement is prohibited under the Stark law.[9]

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[6] Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2011) (http://medpac.gov/docs/default-source/reports/Jun11_EntireReport.pdf).

[7] Government Accountability Office, *Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions* (September 28, 2012) (GAO-12-966); Government Accountability Office, *Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer* (June 24, 2013) (GAO-13-445); Government Accountability Office, *Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny* (July 19, 2013) (GAO-13-525); Government Accountability Office, *Self-Referring Providers Generally Referred More Beneficiaries but Fewer Services per Beneficiary* (June 2, 2014) (GAO-14-270).

[8] 41 C.F.R. 411.357.

[9] Centers for Medicare & Medicaid Services, Advisory Opinions (www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html).

On June 20, 2018, HHS released a Request for Information (RFI) soliciting public feedback on potential changes to the Stark law.[10] The RFI requests information on how Stark law affects providers participating in Alternative Payment Models (APMs), and what could be done to change Stark to promote APMs.

C. The Anti-Kickback Statute

The Anti-Kickback Statute (AKS) prohibits providers from offering, paying, soliciting, or receiving anything of value in order to induce referrals or generate federal health care program business. Like the Stark law, it is intended to prevent provider financial interests from interfering with clinical decisions that can lead to overutilization of health care services, or services that are not in a patient's best interests. Unlike the Stark law, AKS requires a showing of intent (i.e. that the provider knowingly and willfully engaged in the prohibited behavior in order to gain referrals), and criminal penalties are associated with violations of the AKS.[11]

The Department of Health and Human Services Office of Inspector General (HHS-OIG) is charged with administrative enforcement of the AKS, and the agency has created a series of safe harbors under the law.[12] HHS-OIG recently issued a RFI on potential changes to the AKS.[13] As with the Stark law, some stakeholders have argued that the AKS may pose a barrier to value-based payment arrangements and have proposed legislative changes and/or proposals for new safe harbors to cover such arrangements.

Overutilization, improper payments, and fraud continue to pose significant challenges to the Medicare Fee-for-Service (FFS) program. According to the GAO, improper payments accounted for $51.9 billion in spending in fiscal year 2017.[14] The Stark and AKS continue to be important tools for those federal prosecutors pursuing and enforcing waste, fraud, and abuse actions and laws against Medicare providers.[15]

D. Telehealth and Telemedicine in the Medicare Program

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[10] Centers for Medicare & Medicaid Services, *Medicare Program; Request for Information Regarding the Physician Self-Referral Law* (June 25, 2018).

[11] Department of Health and Human Services, Office of Inspector General, Comparison of the Anti-Kickback Statute and Stark Law (https://oig.hhs.gov/compliance/provider-compliance-training/files/starkandakscharthandout508.pdf).

[12] Department of Health and Human Services, Office of Inspector General, *Safe Harbor Regulations* (https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp).

[13] Department of Health and Human Services, Office of Inspector General, *Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP* (Aug. 27, 2018).

[14] Government Accountability Office, *Reducing Government-Wide Improper Payments* (www.gao.gov/key_issues/reducing_government-wide_improper_payments/issue_summary).

[15] Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2017* (Apr. 2018).

Many stakeholders believe telehealth has the potential to improve patient outcomes, by facilitating follow-up care, helping patients manage chronic diseases, and alleviating provider shortages.[16] One of the major barriers to greater telehealth adoption is the limited reimbursement for such services delivered via telehealth in the Medicare FFS program. Healthcare providers must meet a number of restrictions to qualify for telemedicine reimbursement under Medicare. They must be one of ten qualifying distant site practitioners (physicians, nurse practitioners, physician assistants, nurse-midwives, clinical nurse specialists, certified registered nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians and nutrition professionals), the patient must be in a rural federally designated health practitioner shortage area (HPSA), they must be using a real-time audio-visual platform and they must use a current CPT/HCPCS code that is approved for use for telehealth by CMS.

In 2016, 108,000 Medicare beneficiaries accounted for over 300,000 telehealth visits totaling $27 million in spending. These amounts were 0.3 percent of Medicare FFS Part B beneficiaries and 0.4 percent of Medicare spending on physician services. These services were most commonly used for basic physician office and mental health services.[17]

The Congressional Budget Office (CBO) notes the difficulties of scoring coverage expansions for telemedicine services in FFS, because evidence about the effects of such coverage are limited.[18] CBO analyzes proposals to expand Medicare coverage of telemedicine on a case-by-case basis, examining available evidence in order to determine whether the particular coverage expansion will result in reduced utilization of more expensive services, such as emergency room visits or hospital physicians, or would increase the use of other services.[19] A related question is whether increased coverage of telehealth services would result in substitution (i.e. replacing in-person visits) or increased utilization under the traditional Medicare program.[20]

Congress led by our Committee has taken a number of bipartisan actions to expand Medicare beneficiaries' access to telehealth services, including expanding reimbursement for telehealth for patients with end-stage renal disease receiving home dialysis, expanding reimbursement for telehealth for diagnosing acute stroke conditions, allowing Medicare Advantage plans to offer telehealth benefits in their annual bids beyond the services covered

[16] Government Accountability Office, *Telehealth and Remote Patient Monitoring Use in Medicare and Selected Federal Programs* (Apr. 2017) (GAO 17-365).

[17] Medicare Payment Advisory Commission, *Mandated Report: Telehealth Services and the Medicare Program* (Mar. 2018).

[18] Congressional Budget Office, *Telemedicine* (July 29, 2015) (www.cbo.gov/publication/50680).

[19] *Id.*

[20] Medicare Payment Advisory Commission, *Mandated Report: Telehealth Services and the Medicare Program* (Mar. 2018).

under FFS Medicare, and waiving the originating site and geographic restrictions within two-sided risk ACO models.[21]

E. Electronic Health Records and Interoperability

Electronic health records (EHRs) play a critical role in delivering value-based care. Effective EHR use can allow providers to document key information about a patient and the services the patient receives, develop a care plan, and coordinate care for the patient. EHRs can also improve a patient's ability to view their own record and interact with their providers. Beyond the individual level, EHR data can also facilitate population health management. A population level analysis of EHR data may be used to identify trends or issues among a certain patient population.

Lack of interoperability of EHRs, or the ability for two systems to exchange data and interpret that data in a way that is easily understood by a user, remains a barrier to value-based care. With improved interoperability providers will be better able to work in teams to coordinate and deliver care as well as understand the needs of their patient populations. The 21st Century Cures Act (Cures Act) contained provisions to improve interoperability as well as the usability and accessibility of EHRs. For example, in January 2018 the Office of the National Coordinator for Health Information Technology (ONC) released the Trusted Exchange Framework and Common Agreement (TEFCA), as required by the Cures Act. This framework is intended to establish a floor for the standards and procedures entities should establish to safely and effectively enable interoperability among different networks.

II. WITNESSES

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[21] Bipartisan Budget Act of 2018, P.L. No. 105-33.

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