U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

September 11, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Examining Barriers to Expanding Innovative Value-Based Care in Medicare"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Thursday, September 13, 2018, at 1:15 p.m. in 2322 Rayburn House Office Building. The hearing is entitled "Examining Barriers to Expanding Innovative Value-Based Care in Medicare."

II. WITNESS

- Michael Robertson, M.D., Chief Medical Officer, Covenant Health Partners;
- Michael Weinstein, M.D., President, Digestive Health Physicians Association;
- Morgan Reed, President, The App Association;
- Nishant Anand, M.D., Chief Medical Officer, Adventist Health System;
- Timothy Peck, M.D., CEO, Call9; and,
- Mary Grealy, President, Healthcare Leadership Council.

This hearing will focus on the ongoing efforts to transition the Medicare program away from fee-for-service and toward various arrangements that enable better care delivery and the integration of new technologies, and the potential need to update federal statutes and regulations in response to this change.

III. BACKGROUND

A. General Overview

Historically, compensation for services in Medicare was based on a fee-for-service model, where a provider was reimbursed for the amount of services provided to the patient. This system of payment can incentivize providers to focus on "amount of care" and cost of care, since that directly impacted a provider's reimbursement. This approach may not align provider

reimbursement incentives with the goals of improving both the value and efficiency of care and health care outcomes.

In recent years, private sector payers and entities have adopted "value-based purchasing." Value-based purchasing rewards providers for focusing on a patient's care coordination, providing the best clinical care for patients, and integrating new technologies that improve patient outcomes. This approach holds promise to reduce patient costs, improve system efficiencies and achieve savings, and create a financial ability to cover new technologies, drugs and devices that might otherwise be cost prohibitive.

The Medicare Access and CHIP Reauthorization Act or "MACRA" (P.L. 114-10) took a significant step toward encouraging the broader use of value-based purchasing within the Medicare program. MACRA encourages providers to move beyond traditional fee-for-service reimbursement by creating incentives to participate in new care delivery models that increase quality and reduce costs. For example, the law built on the existing Medicare Shared Savings Program (MSSP) to encourage the formation of accountable care organizations (ACOs). Under MACRA, starting in 2019, Medicare providers (who are not exempt from requirements due to their small number of Medicare patients or billing) must participate in either the Merit-Based Incentive Payment System (MIPS) or an Advanced Alternative Payment Model, both options are value-based systems.[1] This dynamic has led providers over the last few years to adopt new care delivery systems that better fit their practice's needs – and that deliver better patient outcomes and allow providers to share in savings.

While some providers want additional payment system models, current options remain limited. The Government Accountability Office (GAO) examined "how federal fraud and abuse laws affect the implementation of financial incentive programs, stakeholders' perspectives on their ability to implement these programs, and alternative approaches through which [the Department of Health and Human Services] has approved implementation of these programs." The GAO concluded that "the laws, regulations, and agency guidance have created challenges for program design and implementation....[as] there are no exceptions or safe harbors specifically for financial incentive programs intended to improve quality and efficiency, and legal experts reported that the constraints of existing exceptions and safe harbors make it difficult to design and implement a comprehensive program for all participating physicians and patient populations."[2]

B. Advanced Alternative Payment Models

An Advanced Alternative Payment Model **(**APM) is a payment model, approved by the Centers for Medicare and Medicaid Services (CMS), that credits participating providers for participating in the MACRA APM. The creation of APMs followed the trend outside of the Medicare program of providers participating in more customized reimbursement systems that better fit their practice and patient's needs. APMs incentivize Medicare providers to adopt these

[1] Some Medicare providers are exempted from these requirements due to their small number of Medicare patients or billing.
[2] https://www.gao.gov/products/GAO-12-355

new models to deliver better patient outcomes and to allow providers to share in the savings generated.

The Committee received testimony that providers participating in APMs are lowering costs, delivering better outcomes, and sharing in savings – which has allowed them to reinvest in efforts to improve patient care.[3] Eligible APMs are required to bear financial risk, require participants to use certified electronic health records (EHR) technology, and maintain a quality measurement component. An APM can be: a Center for Medicaid and Medicare Innovation (CMMI) created program, a Medicare shared savings program accountable care organization (ACO), a demonstration under Section 1866C of the Social Security Act, or a demonstration required by federal statute. The Physician-Focused Payment Models Technical Advisory Committee (PTAC) was created to assist in the development of APMs. PTAC advises and evaluates potential APMs and gives comments and recommendations to the Secretary of HHS as to whether the submitted APMs qualify under the given criteria.

C. Stark Law

Enacted in 1989, *The Ethics in Patient Referrals Act* (P.L. 101-239), the "Stark Law" prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the provider (or an immediate family member) has a financial relationship (absent an exception). A "financial relationship" under the Stark Law includes either (1) an "ownership or investment interest" in the entity or (2) a "compensation arrangement" between the physician (or an immediate family member) and the entity. Since 1989, the Stark Law has evolved through additional legislation and regulations to prevent providers from gaming fee-for-service Medicare by referring patients for unnecessary tests or procedures if the provider could financially benefit from such referral. As Medicare evolves away from the fee-for-service model, there are questions about the Stark Law's impact in a value-based health care model. On June 20, 2018, CMS issued a Request for Information (RFI) regarding the impact of the Stark Law, in part focusing on how the law may impede care coordination.[4] Care coordination is a vital part of value-based care, impacting participation in APMs and innovative care delivery models.

D. Anti-Kickback and Safe Harbors

The Social Security Amendments of 1972, created a federal Anti-Kickback statute (P.L. 92-603) that prohibits the offering, paying, soliciting, or receiving anything of value in exchange for the referral of business in the federal health care programs. The Anti-Kickback statute applies to all health care stakeholders, including providers, drug and device manufacturers, and health plans. Like the Stark Law, there are questions regarding the impact of the Anti-Kickback statute on the evolution towards value-based care. For example, a provider is not allowed to provide a patient with a digital means that allows a patient to communicate with the provider for the purpose of monitoring care and keeping medical complications and costs in check.

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[3] https://energycommerce.house.gov/hearings/macra-alternative-payment-models-developing-options-value-based-care/

[4] https://www.federalregister.gov/documents/2018/06/25/2018-13529/medicare-program-request-for-information-regarding-the-physician-self-referral-law

There are some limited exceptions to the Anti-Kickback statue. The Department of Health and Human Services' Office of Inspector General (OIG) has promulgated regulations that contain several "safe harbors" to prevent common business arrangements from being considered kickbacks. Safe harbors listed by regulation include certain types of investment interests, personal services and management contracts, referral services, and space rental or equipment rental arrangements. OIG updates and amends current safe harbors under the Anti-Kickback statue periodically, as well as adds new safe harbors through a public notice and comment rule making process. However, rules adding new safe harbors can be infrequent, with only three of such rules being finalized in the last ten years.[5]

OIG also issues advisory opinions about the application of Anti-Kickback and other fraud and abuse statutes to a party's existing or proposed business arrangements upon request. These opinions are binding legal opinions, and any arrangement receiving a favorable opinion is protected from OIG sanctions.[6] CMS has also issued a separate RFI seeking comment on potential modifications or additions of new safe harbors to the Anti-Kickback statue.[7]

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact James "J.P." Paluskiewicz, Jay Gulshen, or Josh Trent of the Committee staff at (202) 225-2927.

[5] https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp
[6] https://oig.hhs.gov/faqs/advisory-opinions-faq.asp
[7] https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-18519.pdf