AMERICAN OSTEOPATHIC ASSOCIATION

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October 25, 2018

David R. Levinson
Inspector General
Department of Health and Human Services
Attention: OIG-0803-N
Room 5513, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, OIG-0803-N

Submitted Electronically via http://www.regulations.gov

Dear Mr. Levinson:

On behalf of the osteopathic medical profession comprising more than 137,000 osteopathic physicians (DOs) and medical students, the undersigned organizations appreciate the opportunity to provide input on how elements of the anti-kickback statute and beneficiary inducement civil monetary penalties (CMP) create barriers to providing coordinated, high-value care. Elements of these laws have become antiquated as our health care system has evolved, and there are steps that the Department of Health and Human Services can take to minimize these barriers.

Following the passage of the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015, which established the Quality Payment Program (QPP), the US health care system's shift towards value-based care accelerated. While we support all efforts to prevent fraud and abuse in the Medicare program as well as efforts to promote a system that incentivizes quality over volume, many elements of the anti-kickback and beneficiary inducement CMP place significant and unnecessary compliance burdens on physicians and prevent them from effectively engaging in value-based arrangements.

Providing patient-centered, high quality care is at the heart of osteopathic medicine. Our physicians partner with their patients to provide coordinated care across the spectrum of health care delivery. As our physicians, who practice across all medical specialties, work to support the shift towards high-value care, there are a number of actions that OIG and CMS can take to provide much needed regulatory relief. Please find suggested regulatory changes in response to several elements of the OIG RFI below.

1. Promoting Care Coordination and Value-Based Care

New Safe Harbors

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Since the passage of MACRA, health care delivery models have become more integrated, while compensation arrangements have also become increasingly complex. MACRA incentivized physicians to coordinate care and follow patients more closely across settings in the care continuum. This has necessitated changes in physician compensation arrangements, with physicians whose practice was once limited to their solo or group practice now making more arrangements with outside hospitals, integrated care networks, hospital owned group practices, and other providers. In the midst of these changes, physicians are challenged with ensuring compliance with anti-kickback statute provisions. While CMS and OIG have waived provisions of fraud and abuse laws to test novel payment models, this approach is piecemeal and only applies to a limited number of models. Greater flexibility from fraud and abuse laws, such as the anti-kickback statute, through a broader safe harbor would foster the development of innovative payment models. This is especially necessary for the development of models that are not hospital-led.

Our organizations would be supportive of a more comprehensive safe harbor that allows for the development and implementation of value-based care models that tie together all elements of health care delivery systems. The safe harbor can be developed to apply to a wide range of arrangements but contain language requiring accountability measures that ensure that reimbursement is tied to the value of the care, services, or products delivered. Ultimately, we believe that opportunities for physician leadership in developing value-based models should be supported, and that physicians should be granted flexibility to participate in a wide range of models without having to be employed by a hospital. Many of the value-based care models that have proliferated in recent years have demonstrated success in improving care quality while reducing service overutilization. These patient-centered goals are also part of the intent behind fraud and abuse laws such as the anti-kickback statute.

Modifications to Existing Safe Harbors

Several existing safe harbors to the anti-kickback statute can be modified to improve the delivery of value-based care. The "Personal Services and Management Contracts" safe harbor (42 CFR 1001.952(d)) poses a challenge to the development of value-based models because of its language stating that any agreements contracting an agent on a part-time basis must specify the schedules of the agent, the charge for the contracted periods of time, and the aggregate compensation that is to be paid to the agent. Further, the compensation cannot take into account the "volume or value of referrals or business otherwise generated between the parties" through federal health programs.

This language poses a barrier in multiple ways, and requires that organizations seek advisory opinions on a case-by-case basis for many arrangements. First, language requiring that part-time contracts specify in advance the intervals to be worked can place an undue operational burden on health care facilities, especially those that contract part-time medical directors. Second, the requirement that aggregate compensation be specified can pose a challenge to the implementation of shared-savings arrangements. OIG has expressed that shared-savings arrangements that pay contracted physicians or physician groups a percentage of any savings created following procedures

does not fit into the section in 42 CFR 1001.952(d) because aggregate compensation cannot be set in advance. In advisory opinion No. 08-09 that discussed a shared-savings model for spine fusion surgeries performed by contracted orthopedic and neurosurgery groups at an academic medical center, OIG stated "the absence of safe harbor protection is not fatal. Instead, the Arrangement [sic] must be subject to case-by-case evaluation" (OIG, 2008). However, this places a significant compliance burden on physicians and physician groups, and it discourages the development of novel, risk-based shared savings models because entities cannot be certain of whether their model would meet all necessary safe harbor requirements.

Further concerning is the language on "volume or value of referrals or business otherwise generated." OIG has issued guidance stating that arrangements that have the potential to reduce services offered to patients "take into account volume or value" and should be submitted for review. We would urge OIG to issue guidance outlining how shared-savings models can be implemented without being considered to "take into account volume or value" of referrals or other business. OIG could also issue regulation further defining "gainsharing" and outlining what elements a shared-savings arrangement must have in order to not qualify as a gainsharing arrangement that violates either the anti-kickback statute or gainsharing CMP. Our organizations believe that shared-savings programs, where care delivery is designed around evidence-based approaches, should be promoted in order to deliver higher value care.

Another safe harbor that we believe could be modified to alleviate burden on physicians is 42 CFR 1001.952(y) relating to electronic health records items and services. As different segments of our health care system become more integrated, the sharing of patient information between providers is becoming increasingly important. To aid in this effort, hospital systems will often donate electronic health record (EHR) technology to providers that they contract with. Our organizations appreciate the exception established in past rulemaking that exempts the donation of EHR platforms and services, as well as electronic prescribing tools, from constituting a form of remuneration that violates the anti-kickback statute. This contributes to building an interoperable EHR infrastructure by providing relief to physicians who may otherwise be unable to afford the significant cost of these technologies.

To further enhance these provisions, our organizations encourage OIG and CMS to remove or lower the requirement that physicians pay 15 percent of the donor's cost for items and services related to the EHR platform. Ensuring that physicians' EHR platforms are interoperable with those of the health facilities or groups that they have practice relationships with is central to enhancing care coordination, and this requirement may discourage physicians from taking advantage of upgrading when offered the opportunity.

2. Beneficiary Engagement- Beneficiary Incentives

As osteopathic physicians, we are trained in "whole person" care. This involves following patients across the health care continuum, supporting well-coordinated care, and facilitating interventions that may extend beyond a single encounter. An important element of this is fostering better patient

behaviors, such as proper nutrition, smoking cessation, and proper medication adherence. We believe that patient engagement or patient incentive programs can be helpful in improving behaviors.

The CMP statute excepts forms of remuneration that "promote access to care and pose low risk of harm to federal health care programs" from the beneficiary inducement CMP. In 2016 rulemaking, OIG clarified that "the form of remuneration does not matter (as long as it is an item or service, and not cash or a cash equivalent, and not a copayment waiver), and could include participation in smoking cessation, nutritional counseling, or disease specific support groups, but the remuneration would have to comply with the other prongs of the exception: It must promote access to items or services that are payable by Medicare or a State health care program and pose a low risk of harm to patients and Federal health care programs" (OIG, 2016). Our organizations appreciated this clarification and welcome opportunities to improve our patients' access to care, ensuring that they can receive comprehensive support for all their health care needs. However, we believe more can be done in this regard.

In its clarification, OIG noted that "many forms of free or reduced-cost services (e.g., free screenings at a health fair or charitable dental program, post-discharge support, chronic care management) could lead the patient to seek follow-up care with the provider or supplier that offered the free service. Assuming the free screenings or health care services are not simply marketing ploys but rather identify or assist with necessary care, they could fit in the exception and be protected." This prohibition poses a challenge to the development of value-based models where outcomes are a factor in determining total payment. It also eliminates opportunities to strengthen care management and engage in preventive medicine. Our organizations would ask for the following changes:

- OIG can identify certain preventive services, such as screening and counselling at health fairs, as posing low risk to federal health programs and supporting access to care.
- OIG can specify that complementary services offered at reduced cost after another service has already been rendered as low risk. In the cases of post-discharge support and chronic care management, if these services are being offered at free or reduced cost by physicians with whom patients have established relationships, risk for abuse is low. If a relationship is already established, the offering of these services is unlikely to encourage a patient to receive follow-up care that they would not have otherwise sought with a particular provider.

We believe that these changes will improve patient outcomes by making preventive services and care for patients with chronic conditions more accessible.

3. Cybersecurity-Related Items and Services

As our health care system becomes increasingly digital, many providers are challenged with meeting the cyber security needs that this brings. Physicians need to be able to easily access the tools necessary to protect sensitive patient information. A recent study led by the American Medical Association found that physicians' top three cybersecurity concerns include "interruption to electronic health records (EHR) access, EHR security (including compromised patient data), and

general patient safety concerns" (AMA, 2017).[1] While safe harbors exist to allow hospitals and other health care organizations to donate EHR technology to physicians and medical groups, a safe harbor does not exist for the donation of the cybersecurity technology necessary for the safe use and maintenance of the EHR technology.

If practices are on the same platform as a health care system or hospital, a smaller group's lack of sufficient protections can place the greater system at risk, jeopardizing countless patients' information. As the healthcare industry increasingly moves towards highly connected, value-based systems that rely on easy information sharing, ensuring patient data is well-protected throughout the digital ecosystem is increasingly important. Our organizations would greatly appreciate a safe harbor that allows organizations to donate cybersecurity technology, systems, and services without the requirement of cost-sharing.

We appreciate this opportunity to share feedback on the anti-kickback statute and beneficiary inducement CMP, and our organizations stand ready to assist HHS in any way we can as it considers updates to related regulations. If you have any questions, please reach out to Lisa Miller, Senior Director of Regulatory Affairs and Policy Engagement, American Osteopathic Association at lmiller@osteopathic.org or (202) 349-8744.

Sincerely,

American Osteopathic Association
American Osteopathic Academy of Orthopedics
American Osteopathic College of Radiology
American Academy of Osteopathy
American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American Osteopathic Academy of Sports Medicine

[1] AMA, *Medical Cybersecurity: A Patient Safety Issue*, (Dec. 2017), *available at* https://www.ama-assn.org/about/medical-cybersecurity-patient-safety-issue.