AMERICAN ACADEMY OF FAMILY PHYSICIANS

November 20, 2019

Alec Alexander, Deputy Administrator and Director
Center for Program Integrity
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Deputy Administrator Alexander:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write in response to the request for information titled, "The Future of Program Integrity" as announced by the Centers for Medicare & Medicaid Services (CMS) on October 21, 2019.

**Program Integrity for Value-Based Payment Programs**

1. What type of opportunities for fraud, waste, and abuse do VBP arrangements present that are similar to or are different from FFS or managed care?
    a. What specific changes should CMS consider as part of its program integrity strategy to fight fraud, waste and abuse related to the VBP programs?
    b. Are there lessons from payments to managed care plans under the Medicare Advantage program that CMS can adopt in monitoring capitated and bundled payment arrangements under FFS?
    c. What lessons can CMS learn from program integrity, beneficiary safety and other factors under the sub-capitated arrangements of private plans in their commercial, Medicaid and Medicare lines of business?

As CMS contemplates ways in which it may reduce fraud, waste, and abuse and improve program integrity, we urge it to focus more on outcomes related to quality and utilization and less on procedural safeguards. Such an approach would be more consistent with the guiding principle of choice and competition in the market based on quality, costs, and outcomes than the current approach of subjecting beneficiaries and physicians to increasingly stringent forms, coverage criteria, and documentation requirements.

In traditional FFS, the focus of Medicare program integrity has been ensuring that payment is made for actual services rendered under conditions consistent with Medicare coverage rules. In short, the focus has been on guarding against overpayment and unnecessary utilization. In VBP arrangements, CMS and other payers are increasingly asking physicians to take financial risk for the services they provide and, in some cases the total cost of care, for attributed patients as the focus becomes less about services rendered and more about the quality outcomes experienced by those attributed



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patients. The program integrity strategy needs to change accordingly. For instance, instead of relying on prior authorizations and other tactics that seek to restrain the volume of services rendered, CMS needs to rely on tactics that ensure appropriate patient attribution and assure patients receive the services needed for positive health outcomes.

3. How can payers ensure that payments in VBP programs accomplish the goals of improving the value of the care provided?

"Value" is a function of quality and cost. Payers can ensure VBP programs improve value by structuring the programs in such a way that they incentivize and reward quality while providing physicians with the necessary flexibility to provide clinically appropriate services in the most cost-effective manner possible. In primary care, this means:

- Prospectively attributing patients to practices, primarily based on patient choice
- Paying for most face-to-face primary care services (e.g. office visits) and non-face-to-face primary care services (e.g. care management) via prospective, risk-adjusted per patient per month payments
- Rewarding high quality care with bonuses
- Increasing the level of investment in primary care
- Incentivizing patients to use primary care by minimizing or eliminating cost-sharing for all primary care services

**Prior Authorization in Medicare FFS**

9. What program integrity activities should CMS consider to ensure that items or services are provided as approved through the prior authorization process?
10. Can clinical decision support tools play a role in prior authorization? If yes, how?
11. How can we apply prior authorization without adding to provider and supplier burden?
12. How can we apply prior authorization while maintaining timely and complete access to medically reasonable and necessary covered services for our beneficiaries?
13. While prior authorization helps ensure that services or items to be furnished comply with all applicable coverage and coding rules at the time of the prior authorization request, some requirements cannot be assessed until after care delivery. What information cannot be captured by a prior authorization process? Does this limit or restrict prior authorization?
14. Are there other issues with respect to prior authorization that CMS should consider?

The AAFP urges CMS to promote policies focused on patient care. The AAFP strongly supports streamlining prior authorization requirements and reducing administrative burden in all health care programs—both public and private. Onerous and unnecessary prior authorization requirements top the list of physician complaints on administrative burdens. This uncompensated work for physicians and staff translates into increased overhead costs for practices, significantly reduced time spent with patients, disruption of workflows that result in costly inefficiencies, and delayed care and worse outcomes – the very results that these VBP arrangements seek to eliminate. According to AMA data, interactions with insurers cost $82,975 annually per physician. Exacerbating this concern is the fact that most family physicians in practice have contractual relationships with seven or more health insurance plans, including Medicare and Medicaid. Even within these contractual relationships, different requirements for different plan types (e.g. PPO, HMO) exist. In coalition with 16 other medical organizations, the AAFP has called for the reform of prior authorization and utilization management requirements that impede patient care in Prior Authorization and Utilization

Management Reform Principles. In addition, the AAFP has published, Principles for Administrative Simplification, calling for an immediate reduction in the regulatory and administrative requirements family physicians and practices must comply with daily. CMS must consult and adhere to these principles.

Yes, clinical decision support tools play a role in prior authorization. The AAFP believes there is a need to semantically model clinical concepts and knowledge so health IT systems can be smarter. Health IT systems need to support clinical decision making. In addition to the semantic data standards, there is the potential of new machine learning (ML) algorithms to support and accelerate semantic modeling. HHS should support the advancement of ML applications to support improved clinical decision support usability. The AAFP has joined Logica Health to establish a community effort to create, recognize, and deploy standardized semantic clinical data models. Additionally, the AAFP is undertaking an effort to engage the artificial intelligence (AI) and ML community to address these issues and looks forward to partnering with HHS in these efforts.

The AAFP worked with leading national organizations representing physicians, medical groups, hospitals, pharmacists, and health plans that developed a consensus statement on prior authorization. It calls for the agency to:

- Create an electronic prior authorization program including the electronic transmission of prior authorization requests and responses and a real-time process for items and services that are routinely approved;
- Improve transparency by requiring plans to report to CMS on the extent of their use of prior authorization and the rate of approvals or denials;
- Require plans to adopt transparent prior authorization programs that are reviewed annually, adhere to evidence-based medical guidelines, and include continuity of care for individuals transitioning between coverage policies to minimize any disruption in care;
- Hold plans accountable for making timely prior authorization determinations and to provide rationales for denials; and
- Prohibit additional prior authorization for medically-necessary services performed during a surgical or invasive procedure that already received, or did not initially require, prior authorization.

The AAFP believes prior authorizations should be standardized, processed in real-time through seamless integration into EHRs, available at no cost to the physician, and universally electronic throughout the industry to promote conformity and reduce administrative burdens. Prior authorizations create significant barriers for family physicians to deliver timely and evidenced-based care to patients by delaying the start or continuation of necessary treatment. At best, these manual, time-consuming processes used in prior authorization programs burden family physicians, divert valuable resources away from direct patient care. At worst, they can inadvertently lead to serious negative clinical outcomes for patients.

The AAFP believes family physicians using appropriate clinical knowledge, training, and experience should be able to prescribe and/or order without being subjected to prior authorizations. The AAFP further believes that a physician's attestation of clinical diagnosis or order should be sufficient documentation of medical necessity for durable medical equipment. In rare circumstances when prior authorizations are clinically relevant, the AAFP believes they should be evidenced-based, transparent, and efficient to ensure timely access and ideal patient outcomes. Additionally, family

physicians that contract with health plans to participate in a financial risk-sharing agreement should be exempt from prior authorizations.

The AAFP believes that generic medications should not require prior authorization. The AAFP further believes step therapy protocols used in prior authorization programs delay access to treatments and hinder adherence. Therefore, the AAFP maintains that step therapy should not be mandatory for patients already on a course of treatment. Ongoing care should continue while prior authorization approvals or step therapy overrides are obtained. Additionally, patients should not be required to repeat or retry step therapy protocols failed under previous benefit plans.

Public and private insurance formularies must be easily accessible and accurate. A 2016 study published in the *Annals of Internal Medicine* found that primary care physicians spent 27 percent of their time on clinical activities and 49 percent on administrative activities. The authors concluded that primary care physicians spend nearly 50 percent of their time on cumbersome administrative tasks such as prior authorization, performance measurement and reporting, electronic health record documentation, and care management documentation. This inefficiency and time diverted from patient care is clearly not acceptable.

**Provider Education**

15. What strategies, tools, or technologies exist to help CMS better connect ordering physicians, rendering providers, and suppliers with respect to their responsibility to provide proper documentation?

Currently, the Office of the National Coordinator for Health Information Technology (ONC) is undertaking a process to fulfill Congress's vision by enabling easier extraction and use of health data from EHRs through application programming interfaces, or APIs. We urge you to support the approach ONC takes in their proposed regulations to help ensure that patients, providers and clinicians have more complete health information wherever and whenever they need it.

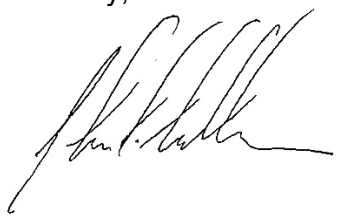
Many of the current challenges to system-wide interoperability can be traced back to a lack of standardization. ONC proposes to address this by requiring use of the Fast Healthcare Interoperability Resources (FHIR) standard, which can make it easier for systems to request specific patient information. Use of the standard would also prevent individual technology developers from implementing proprietary APIs that make it more difficult to exchange data. In finalizing the proposed rule, ONC should maintain its commitment to FHIR-based APIs. In addition, ONC should adopt the most recent version of the standard—called Release 4—as it is not expected to significantly change in future iterations for some time. Please review a letter the AAFP and others sent Congress on September 11, 2019, for further details.

16. What strategies, tools, or technologies exist to help providers and suppliers become more aware of the necessary documentation requirements earlier in the claim process?

The AAFP calls on CMS to work with national physician organizations to educate practicing physicians on ways to properly document medical records while avoiding time-consuming prior authorizations. The AAFP stands ready to work with CMS in this capacity and has multiple channels for communicating with and educating our members on this subject.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 or rbennett@aafp.org with any questions.

Sincerely,



John S. Cullen, MD, FAAFP
Board Chair