February 5, 2016

The Honorable Orrin Hatch
Chairman, Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Kevin Brady
Chairman, House Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

RE: Implementation of MACRA and the Stark Law

Dear Chairmen Hatch and Brady:

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I write in response to your request for information on the Stark Law. Specifically, you have requested information from stakeholders about "what changes need to be made to the Stark Law to implement MACRA (Medicare Access and CHIP Reauthorization Act of 2015) in its current form and ACOs / shared savings programs." The AAFP thanks you for your leadership on this important topic and submits the following comments for the Committees' consideration:

The AAFP is grateful to bipartisan Congressional leadership that resulted in the passage of MACRA in April 2015. The AAFP endorsed MACRA, which has established a reformed fee-for-service system for physician payment (The Merit-Based Incentive Payment System, or MIPS), as well as an avenue for physicians to be paid under one or more alternative payment models (APMs). In addition to providing these multiple avenues for payment and delivery reform, MACRA also stabilized Medicare physician payment by repealing the flawed Sustainable Growth Rate (SGR) Formula. As the Centers for Medicare and Medicaid Services (CMS) begins to implement MACRA this year, the AAFP appreciates the Committees' ongoing attention to the potential interplay between MACRA and the Stark law. **In brief, although the AAFP does not yet foresee any necessary articulable modifications to the Stark Law or related waiver authorities to smooth the path for MACRA implementation, we believe that Congress should continue to closely monitor and evaluate the potential impact of the Stark Law on innovations in health care delivery and payment. The AAFP urges Congress to ensure that the Stark Law does not hinder family physicians' ability to transform their practices and collaborate with other physicians and health care professionals to provide team-based, patient-centered care that incorporates new technologies and focuses on reducing the total cost of care.**

America's family physicians generate a significant volume of referrals for services within the Medicare program. According to the National Ambulatory Medical Care Survey, in 2012 (the most recent year for which data is available), family physicians generated 24.2 percent of all referrals to services (including examinations, lab tests, imaging, etc.) arising out of Medicare office visits. As such, family medicine practices frequently seek professional advice when they add lines of service to their own practices (e.g. laboratory services, physical or nutritional therapy, as well as imaging), if they plan to refer their own

Medicare patients to such services. Family physicians often can refer their patients within the practice in compliance with the Stark Law, under the in-office ancillary services (IOAS) exception.[1]

Alternative Payment Models (APMs)

As with existing alternative payment models such as Medicare Accountable Care Organizations, the AAFP expects APMs under MACRA to accelerate the need to coordinate and integrate care across payment and delivery settings—and will likely give rise to substantial need for waivers for physicians from the Stark Law. However, because MACRA relies entirely on existing statutory authority to generate APMs, the AAFP does not yet foresee a need for new authority to waive the Stark Law. Under MACRA, physicians will be considered qualifying or partially-qualifying APM participants in a certain year if they receive revenue (either Part B only or Part B in combination with other revenue) for that year through an eligible APM, beyond a statutorily defined threshold. An eligible APM under MACRA must be one of the following: (1) A model under section 1115A (other than a health care innovation award), (2) the shared savings program under section 1899, (3) a demonstration under section 1866C, or (4) a demonstration required by federal law. At this time, HHS has the appropriate waiver authority for each of the first three, and for the fourth depending on the demonstration at issue.

- First, Section 1115A of *the Social Security Act* (which establishes the Center for Medicare and Medicaid Innovation or CMMI), under subsection (d)(1), grants the Secretary explicit authority to waive requirements of title 18, including the Stark law, "as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)." Accordingly, the Secretary already has the broadest possible Stark Law waiver authority for models tested and expanded by CMMI.

- Second, Section 1899 of *the Social Security Act* (which establishes the Medicare Shared Savings Program, or MSSP), under subsection (f), grants the Secretary explicit authority to waive requirements of title 18, including the Stark law, "as may be necessary to carry out the provisions of this section." Accordingly, no additional waiver authority ought to be needed to continue implementing the MSSP.

- Third, Section 1866C of *the Social Security Act* (which establishes the Health Care Quality Demonstration Program), under subsection (e), grants the Secretary explicit authority to waive requirements of title 18, "as may be necessary to carry out the purposes of the demonstration program established under this section." Hence, no additional waiver authority ought to be needed to implement this demonstration.

- Finally, a "demonstration required by federal law" is a catch-all that could refer to a number of legacy demonstration projects, for example the Independence at Home Demonstration Program under Section 1866E of *the Social Security Act*, or the National Pilot Program on Payment Bundling under Section 1866D of *the Social Security Act*. This catch-all language could also embrace demonstrations that Congress enacts at a later date. Whether the Secretary has authority to waive the Stark law for any of these demonstrations will turn on the question of whether Congress granted such authority for that demonstration program at issue. (For example, CMS does not have waiver authority in connection with the Independence at Home Demonstration Program, while it does for the Payment Bundling Demonstration Program.)

[1] Although not the explicit topic of this RFI, the AAFP would as an aside urge the Committees to preserve the current scope of the IOAS exception, in order to allow Medicare beneficiaries to continue to benefit from the salutary features of the patient-centered medical home (PCMH). Under the PCMH delivery model, family- and other primary-care physicians deliver coordinated and integrated care—taking responsibility for the patient's entire health-care needs—in a single practice, often relying on multiple services within the PCMH, as well as referring to multiple elements of the health-care system outside the PCMH (e.g. other physicians, hospitals, post-acute care).

While HHS has not yet classified any payment models as MACRA APMs, the AAFP anticipates that most models that HHS will select will be tested and expanded under Section 1115A of *the Social Security Act* (i.e. through the CMMI authority). Existing models being tested under Section 1115A specific to primary care include the Comprehensive Primary Care Initiative (CPCI), the Multi-Payer Advanced Primary Care Practice Demonstration (MAPCP), and the Federally Qualified Health Center Advanced Primary Care Practice Demonstration. In addition, the Pioneer ACO Program is being tested under CMMI authority. Whether these become MACRA APMs is an open question—but regardless, CMS has broad authority to waive the Stark Law for any of them, under Section 1115A. Similarly, CMS has broad waiver authority for the MSSP program, and for the Health Care Quality Demonstration Program. Finally, of the individual demonstrations required by federal law, the AAFP is not aware of any specific demonstration that requires a grant of waiver authority in order for it to succeed as a MACRA APM. The AAFP expects HHS to continue to use its waiver authority under MACRA, as it has under several of these demonstration programs.

It should be noted that MACRA contemplates the development of APMs through other avenues—for example, a Physician-Focused Payment Model Technical Advisory Committee (TAC), established under Section 1868 of *the Social Security Act*. The TAC, which held its first meeting on Monday, February 1, is charged with reviewing proposals for payment models, and on a periodic basis, submitting comments and recommendations to the Secretary. However, because the Secretary ultimately retains responsibility for establishing APMs, the work of the TAC will not have any independent Stark-related implications. Ultimately, even if the TAC develops APMs, they must be vetted by the Secretary, and tested through CMMI in order to become MACRA APMs.

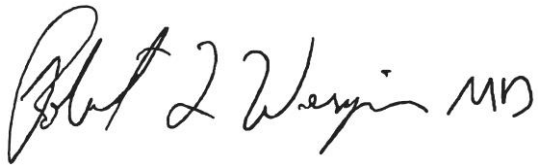
Finally, MACRA also requires the Department of Health and Human Services to deliver a report to Congress no later than two years after enactment (April 2017), examining the interaction of the federal fraud prevention laws with items and services delivered under MACRA APMs. This report will provide the Committees with helpful additional information about the agency's experience with the fraud and abuse waivers that it has issued under its existing authority to implement the MSSP, ACO, and other programs that could be designated as MACRA APMs.

Merit-Based Incentive Payment System

As with APMs, the AAFP does not yet foresee a concrete need to amend the Stark Law to facilitate implementation of MIPS. MIPS consolidates four Medicare quality programs into a single program: the Physician Quality Reporting System (PQRS), Meaningful Use of Certified EHR Technology (Meaningful Use), and Value-Based Payment Modifier (VM), which are currently in operation, as well as Clinical Practice Improvement Activities—expected to be launched in 2017. While the details of MIPS implementation will depend largely on CMS's design, the AAFP does not view the MIPS framework as substantially different from existing fee-for-service payment such that it will impact the application of the Stark Law on family-physician referral patterns. However, the AAFP advises the Committees to closely monitor two issues: First, the complexity of MIPS may accelerate the current consolidation of health systems with independent physician practices—if independent practices struggle to meet the additional administrative burden imposed on them by MIPS. Second, MIPS gives practices the authority to combine into "voluntary virtual groups" for MIPS reporting and payment purposes. To the extent that physician practices within such virtual groups might need safe harbor from the Stark Law (for example, if they begin to exhibit certain characteristics of a group practice, yet are not eligible for the "group practice" exception to the Stark Law), the Committee should closely monitor that as CMS implements the MIPS virtual groups.

Thank you for the opportunity to submit these comments. For any questions you might have about the AAFP's perspectives please have your staff contact Andrew Adair, Government Relations Representative, at aadair@aafp.org.

Sincerely,



Robert L. Wergin, MD, FAAFP
Board Chair

Cc: Chairman Peter Roskam, Oversight Subcommittee, House Committee on Ways and Means