AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

January 16, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4182–P
P.O. Box 8013
Baltimore, MD 21244–8013

Dear Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the proposed rule "Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" as published by the Centers for Medicare & Medicaid Services (CMS) in the November 28, 2017 *Federal Register*.

We appreciate that CMS is revising the Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to make improvements and implement provisions of the *Comprehensive Addiction and Recovery Act* (CARA) and the *21st Century Cures Act*. We offer the following comments to improve further these programs' quality, accessibility, and affordability.

II. Provisions of the Proposed Regulations

A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

Summary

CMS proposes to implement new CARA requirements so as to provide an important additional tool to combat the growing opioid epidemic that is devastating families and communities across the nation. CARA requires CMS to establish through regulation a framework that allows Part D sponsors to voluntarily implement a drug management program that limits "at risk" beneficiaries' access to controlled substances that CMS determines are "frequently abused drugs" beginning with the 2019 plan year. CMS proposes to designate opioids (with limited exceptions) as frequently abused drugs; tie the definition of at-risk beneficiaries to the criteria used to identify potential opioid overutilizers under CMS' existing Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS); and allow a plan to limit an at-risk beneficiary's access to opioids to a selected prescriber(s) and/or network pharmacy(ies), which would be an extension of CMS' DUR policy and OMS. CMS also proposes to exempt beneficiaries who have cancer or are in hospice or long-term care from the drug management program. CMS proposes to limit the availability of the special enrollment period (SEP) for dually- or other low-income subsidy (LIS)-eligible beneficiaries who are identified as at-risk or potentially at-risk for prescription drug abuse under such a drug management program. At-risk determinations and any associated limitations on access to frequently abused drugs would be subject to the existing beneficiary appeals process.

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AAFP Response
In general, the AAFP is supportive of the provisions in the proposed rule to implement sections of CARA in regard to managed care plans. The AAFP realizes that there are patients with inappropriate drug-seeking behavior. However, it is not always clear who these individuals are absent a database containing this information.

The drug management plans outlined in the proposed rule attempt to work around the lack of interoperability of electronic health records (EHRs) and prescription drug monitoring programs (PDMPs) by providing a framework for sponsors to identify "at-risk" beneficiaries. The AAFP continues to strongly advocate for effective state PDMPs that facilitate the interstate exchange of registry information as called for under the *National All Schedules Prescription Electronic Reporting Act*. We advocate for physicians to use their state PDMP before prescribing any potentially abused pharmaceutical product. However, the success of such efforts depends on state reporting systems that are accessible, timely, and interoperable. We urge CMS to work with other sectors at the national and state level to help make these systems more effective for the sake of the public health.

The AAFP is supportive of the proposed guidelines used to confirm "at-risk" individuals based on daily use of 90 morphine milligram equivalents or higher of opioids and multiple opioid prescribers and pharmacies. The AAFP is also supportive of the proposed case management and prescriber verification before enacting limits on coverage of prescription medication. This is a crucial step to verify the accuracy of the information and to inform clinicians of beneficiaries who are receiving opioid prescriptions from multiple prescribers. As outlined above, this is a result of the lack of interoperability of state PDMPs. The AAFP opposes actions that unnecessarily limit patients' access to pharmaceuticals prescribed by a physician using appropriate clinical training and knowledge. Family physicians and other primary care clinicians play a vital role in effective pain management, which may include opioid analgesics.

The AAFP has concerns with regard to the proposed rules regarding notices to beneficiaries about possible limits on access to coverage for opioids. The AAFP agrees that sponsors should be required to notify beneficiaries, but the AAFP would like the notifications to be written at the appropriate health literacy level and to set up an opportunity for the beneficiaries to speak with a clinician to obtain substance use disorder treatment as appropriate. There is concern that a written letter may not provide the best vehicle for some beneficiaries to obtain the services they need.

The AAFP encourages CMS to require plans to support the use of evidence-based treatments for substance use disorders including medication assisted treatment.

8. Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries
Summary
CMS proposes to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated Dual Eligible Special Need Plans (D-SNP) into another integrated D–SNP when a beneficiary does not make an alternative coverage choice. CMS also proposes to receive passive enrollments under the new authority, Medicare Advantage plans must be highly integrated, required to have substantially similar provider and facility networks, and must have a minimum of three MA stars rating. Low enrollment contracts or new plans without MA Star Ratings would also be eligible if the plan meets all other proposed requirements. CMS recognizes that MA Star Ratings do not

capture performance for those services that would be covered under Medicaid. CMS seeks comment on what measures and minimum ratings would best serve CMS' goal in this proposal. Furthermore, CMS states that under the Financial Alignment Initiative demonstrations, states are required to provide two passive enrollment notices. CMS does not propose to modify the existing notification requirements under this demonstration. However, CMS is requesting comment on alternatives regarding beneficiary notices, including content and timing of such notices.

AAFP Response
The AAFP prefers patients be given free choice of plan selection. However, when patients do not make an alternative coverage choice, the AAFP supports CMS' proposal to passively enroll patients but only if the patient's primary care physician is participating in the network. The AAFP strongly believes existing relationships with the patient's primary care physician should be maintained. Patients who have a continuous and longitudinal relationship with a primary care physician have better health care outcomes at lower costs than those who do not have such a relationship. To protect these relationships, the AAFP suggests CMS use recent claims data to identify each patient's key physician and assign the patient to the plan that includes those physicians in its network.

Regarding passive enrollment notification, CMS states that under the Federal Alignment Initiative, states are currently required to provide two passive enrollment notices. CMS would encourage but not require a second notice or additional outreach to impacted individuals. The AAFP believes the two notices provided under the Federal Alignment Initiative are sufficient. However, the AAFP believes the patient choices section of the letter should be further highlighted to draw greater attention. Further, the AAFP believes the notice should also include whether the patient's primary care physician and other previously seen clinicians, within a twenty-four month look back period, are in-network. In addition, regardless of whether the patient actively or passively enrolls, the patient's primary care physician and other clinicians should be notified of the patient's change in insurance.

The AAFP is concerned with passively enrolling patients in low enrollment contracts or plans without MA Star Ratings. Patients may have chosen the previous plan based on Star Ratings. Passively enrolling patients in plans with no Star Rating could disregard their previous thoughtful determination. According to a Kaiser Brief, "In 2017, 66 percent of MA enrollees are in plans with 4 or more stars." The AAFP believes this indicates that most MA enrollees choose plans based on Star Ratings and passively enrolling patients in a plan with no star rating would disregard the patient's initial consideration. Therefore, the AAFP believes that patients should be passively enrolled in plans with the same number of stars as their previous plan or more.

In terms of measures, the AAFP believes only measures developed by the multi-stakeholder Core Quality Measures Collaborative should be used. This ensures alignment, harmonization, and the avoidance of competing quality measures among public and private payers. Physicians, especially family physicians, bear the brunt of quality and performance measurement. A major part of this load is the burden of multiple performance measures in quality improvement programs with no standardization or harmonization.

9. Part D Tiering Exceptions
Summary
Currently, patients enrolled in a Part D plan with a tiered formulary may request an exception to the plan sponsor's tiered cost-sharing structure. These procedures permit enrollees, under certain circumstances, to obtain a drug in a higher cost-sharing tier at the more favorable cost-sharing

applicable to alternative drugs on a lower cost-sharing tier of the plan sponsor's formulary. An exception is granted when the plan sponsor determines that the non-preferred drug is medically necessary based on the prescriber's supporting statement. CMS reiterates that products on the specialty tier are not eligible for a tier exception.

At the start of the program, most Part D formularies included no more than four cost-sharing tiers, generally with only one generic tier. Since that time, there have been substantial changes in the prescription drug landscape, including increasing costs of some generic drugs, as well as the considerable impact of high-cost drugs on the Part D program. Plan sponsors have responded by modifying their formularies and Plan Benefit Packages (PBPs), resulting in the increased use of two generic-labeled drug tiers and mixed drug tiers that include brand and generic products on the same tiers. These changes and increased complexities lead CMS to believe that their current regulations are no longer sufficient to ensure that tiering exceptions are understood by patients and adjudicated by plan sponsors in the manner the statute contemplates.

Because of the increases in complex tiering structures, CMS states Part D sponsors have been considering any tier that is labeled generic to be exempt from tiering exceptions if the tier also contains brand name drugs. CMS further states that it has become even more problematic with the increase in the number of PBPs with more than one tier labeled generic.

CMS proposes that plans would be required to approve tiering exceptions for non-preferred generic drugs when the plan determines that the enrollee cannot take the preferred generic alternative(s), including when the preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives.

AAFP Response
As the healthcare landscape continues to move toward value based payment, the AAFP believes services such as patient medications should be provided at minimal or no cost-sharing. The AAFP's Value Based Insurance Design (VBID) policy states in part, "VBID is a strategy that minimizes or eliminates out-of-pocket costs for high-value services in defined patient populations. The primary objective of VBID is to reduce and eventually eliminate financial barriers to high-value health care services." VBID should encourage beneficiaries, with chronic conditions, to seek out and receive the care they need before ending up in the emergency room or hospital.

Accordingly, within MA and Medicaid managed care programs, there exists an extremely vulnerable population where Part D cost-sharing keeps patients from being compliant. Many patients miss taking their drugs or ration their medications to delay the cost of renewing their prescription. While the AAFP agrees with CMS' proposals as it would assist patients with lower cost-sharing for needed medications while also advancing VBID, the AAFP urges CMS to review their current specialty tier policies.

CMS reiterates in the proposed rule that products on the specialty tier are not eligible for a tier exception. The increasing use of specialty tiers has negative implications on patients. For example, certain conditions have therapeutic options that all fall under the specialty tier with higher cost-sharing for patients. For all other plan formulary tiers, beneficiaries may file an exception for a drug to be placed on a lower cost-sharing tier, if the medication is the only therapy available for their disease. Specialty tier drugs are the sole exception to this, even though these drugs often have the most

burdensome cost-sharing requirements. The AAFP believes a mechanism should be created that would allow patients to file an exception for specialty drugs was well.

While not discussed in the proposed rule, the AAFP believes the $670 specialty tier threshold should be increased. The AAFP is concerned that the specialty tier threshold does not take into consideration the effects of inflation on drug prices or the growing number of high-cost specialty drugs. Patients typically face higher out-of-pocket costs for specialty tier drugs because plans are more likely to require patients to pay a coinsurance rate for expensive drugs rather than a flat copayment to access these drugs. Keeping the specialty tier threshold low means that more drugs fit into this tier, which raises costs for Part D plan enrollees and makes it harder for them to afford needed medications.

10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries
Summary
To ensure that Part D plan sponsors can administer benefits, including coordination of Medicare and Medicaid benefits, CMS proposes to change the Special Election Period (SEP) for dual-eligible and LIS beneficiaries from an open-ended monthly SEP to one that may be used only in the following circumstances (and only if the beneficiary has not been identified as potentially at-risk or at-risk):

1. Within a certain period of time after a CMS or State-initiated enrollment; or
2. As a onetime annual opportunity that can be used at any time of the year. CMS proposes to establish a separate SEP that can be used by any dual or other LIS-eligible beneficiary, including those who have been identified as potentially at-risk or at-risk, within a certain period of time after a change to an individual's LIS or Medicaid status.

AAFP Response
We are concerned with limiting SEPs for dual eligible beneficiaries since these individuals often have the greatest need for health care services. Similar to our comments on passive enrollment, the AAFP prefers patients be given free choice of Part D plan selection regardless of whether a SEP is monthly or annually. However, when patients do not make an active choice, the AAFP encourages CMS, states, and plans to help these patients enroll in plans that cover the patient's current medications so that the patient's primary care physician is not subjected to additional Part D prior authorization hassles.

B. Improving the CMS Customer Experience
Summary
The *21st Century Cures Act* eliminates the existing MA disenrollment period that currently takes place from January 1st through February 14th of every year and, effective for 2019, replaces it with a new MA open enrollment period (OEP) that will take place from January 1st through March 31st annually. The new OEP allows individuals enrolled in an MA plan to make a one-time election to go to another MA plan or Original Medicare. Individuals using the OEP to make a change may make a coordinating change to add or drop Part D coverage.

AAFP Response
The AAFP agrees with this CMS proposal.

2. Reducing the Burden of the Compliance Program Training Requirement
Summary

CMS proposes to delete the regulatory provision that requires acceptance of CMS' training as meeting the compliance training requirements but also the reference to first-tier, downstream, and related entities (FDRs) in the compliance training requirement. CMS justifies this proposal by maintaining that the industry has accumulated program experience, the growing sophistication of the industry compliance operations, as well as their continuing requirements on sponsors for oversight and monitoring of FDRs. CMS will continue to hold MA organizations and Part D sponsors accountable for their FDRs to comply with Medicare program requirements. Compliance training would still be required of MA and Part D sponsors, their employees, chief executives or senior administrators, managers, and governing body members.

AAFP Response
The AAFP agrees with these CMS proposals if CMS continues to offer their compliance training as a resource and benchmark for other compliance training resources.

3. Medicare Advantage Plan Minimum Enrollment Waiver
Summary
CMS is proposing that the waiver of the minimum enrollment requirement may be in effect for the first 3 years of the contract. Further, CMS is proposing that they would only review and approve waiver requests during the contract application process. CMS would also propose to remove the requirement for MA organizations to submit an additional minimum enrollment waiver annually for the second and third years of the contract.

AAFP Response
The AAFP is concerned that if MA organizations are no longer required to submit the minimum enrollment waiver in the second and third years of the contract, these organizations could neglect to develop strategies to market and enlarge their patient enrollment.

4. Revisions to Timing and Method of Disclosure Requirements
Summary
CMS commented that the Pew Research Center found that most American adults age 65 and older use the internet and have access to broadband available at home. The Center also found internet use increases even more among seniors age 65-69. CMS further commented that electronic documents include advantages such as word search tools, the ability to magnify text, screen reader capabilities, and bookmarks or embedded links, all of which make documents easier to navigate. CMS lastly mentioned that given that the younger range of Medicare beneficiaries have a higher rate of internet access, CMS believes the number of beneficiaries who use the internet will only continue to grow with time.

Therefore, CMS proposes to provide flexibility to MA plans and Part D sponsors to use technology to provide beneficiaries with information. CMS intends to use this flexibility to provide sponsoring organizations with the ability to electronically deliver plan documents (for example, the Summary of Benefits) to enrollees while maintaining the protection of a hard copy for any enrollee who requests such hard copy. CMS believes this proposal will ultimately result in reducing burden and providing more flexibility for sponsoring organizations. CMS will still require MA plans and part D sponsors to provide the Annual Notice of Change at least 15 days before the Annual Enrollment Period.

AAFP Response
The AAFP agrees with this CMS proposal.

10. Part D Prescriber Preclusion List

Summary

In May of 2015, CMS begun implementation of Section 6405(c) of the *Affordable Care Act*, which requires that prescriptions for covered Part D drugs be prescribed by a physician enrolled in Medicare or an otherwise eligible professional. The purpose of this policy is to help ensure that Part D drugs are prescribed only by qualified prescribers. In this regulation, CMS proposes to delete the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim for a Part D drug prescribed by a physician or eligible
professional to be covered. Instead, CMS proposes compiling a "Preclusion List" of individuals and entities that fall within either of the following categories:

1. Currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or
2. Have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

The preclusion list would be updated monthly based on CMS' internal data. Under this option, CMS would make the Preclusion List available to Part D prescription drug plans and Medicare Advantage plans. Plans would then be required to deny claims from or written by prescribers and providers on the list. CMS proposes to permit prescribers who are on the preclusion list to appeal their inclusion on this list.

AAFP Response

Though the vast majority of AAFP members are already enrolled and participate in the Medicare program, the AAFP in previous comment letters opposed requiring physicians who write prescriptions for covered Part D drugs to be enrolled in Medicare for their prescriptions to be covered under Part D. While we recognized that CMS was implementing Section 6405 of the *Affordable Care Act*, our opposition of the current policy was not out of the increased and unfunded administrative burden it imposes, but rather based on the belief that the Medicare covenant is between the beneficiary and the program and that Medicare benefits belong to the beneficiary. We are therefore thankful that CMS is taking a new approach to this process rather than the requirement of Medicare enrollment. .

However, prescribing authority is already tied to the physician having a U.S. Drug Enforcement Administration (DEA) number and not a National Provider Identifier. Since physicians must already establish a relationship with the federal government through the DEA to prescribe, the AAFP continues to encourage CMS to explore implementation of these policies though closer coordination with the DEA.

This AAFP reaction is the same for the proposed changes for the Part C/Medicare Advantage Cost Plan and PACE Preclusion List.

13. Reducing Provider Burden—Comment Solicitation

Summary

Without proposing any changes, CMS solicits feedback on ways to reduce burden on institutions, physicians, and other practitioners arising from requests for medical record documentation by MA

organizations. CMS is interested in stakeholder feedback on the nature and extent of this burden of producing medical record documentation and on ideas to address the burden. CMS notes they are particularly interested in burden experienced by solo providers.

AAFP Response
The AAFP appreciates that the agency seeks comments on ways to further reduce the administrative and regulatory burdens family physicians face daily with the Part C program. The AAFP urges CMS and MA plans to focus more on outcomes related to quality and cost 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.

The AAFP developed the following prioritized list of principles on administrative simplification. Adherence to these principles will ensure that patients have timely access to treatment while reducing administrative burden on physicians. Additional ways CMS and MA plans could reduce administrative and regulatory burdens for family physicians and solo- and small practices include:

1. Prior Authorization
Physicians strive to deliver high-quality medical care in an efficient manner. The frequent phone calls, faxes, and forms physicians and their staff must manage to obtain prior authorizations (PAs) from prescription drug plans and durable medical equipment suppliers, and others impede this goal.

Principles:
- Activities requiring prior authorization (PA) must be justified in terms of financial recovery, cost of administration, workflow burden, and lack of another feasible method of utilization control.
- Rules and criteria for PA determination must be transparent and available to the prescribing physician, at the point of care. If a service or medication is denied, the reviewing entity should provide the physician with the criteria for denial. For medications, it should provide alternative choices to eliminate a guessing game.
- PA for imaging services should be eliminated for physicians with aligned financial incentives (e.g. shared savings, etc.) and proven successful stewardship.
- There should be a goal of eliminating PA for durable medical equipment (DME), supplies, and generic drugs.

Transitional steps include:
- Limiting and reducing the number of products and services requiring PA.
- Adopting a standardized form and process for PA among all payers.
- Requiring payers and pharmacy benefit managers (PBMs) that design PA specifically to save the payer or PBM money rather than benefit the patient to pay physicians for their time, as decided by the 2008 Merck-Medco v. Gibson court case.
- Requiring payers to pay physicians for PAs that exceed a specified number of prescriptions or are not resolved within a set time-period.
- Prohibiting payers from requiring repeated PAs for effective medication management for patients with chronic disease and PA for standard and inexpensive drugs.

2. Quality Measures and the Need for Measure Harmonization

Quality measures have proliferated in the past 15 years, leading to a significant compliance burden for physicians. Most of the measures are disease-specific process measures, rather than more meaningful evidence-based outcomes measures. With many family physicians submitting claims to more than 10 payers, the adoption of a single set of quality measures across all public and private payers is critical.

Principles:

- Quality measures should be focused on improving processes and outcomes of care in terms that matter to patients.
- Quality measures should be based on best evidence and reflect variations in care consistent with appropriate professional judgment.
- Quality measures should be practical given variations of systems and resources available across practice settings.
- Quality measures should not separately evaluate cost of care from quality and appropriateness.
- Payers should take into account the burden of data collection, particularly in the aggregation of multiple measures.
- Payers should provide transparency for methodology used to rate or rank physicians.
- All payers (Medicare, Medicaid, Veterans Administration, commercial insurers, ERISA plans, and any third-party administrator plan) should implement the core measure sets developed by the multi-stakeholder Core Quality Measures Collaborative to ensure parsimony, alignment, harmonization, and the avoidance of competing quality measures.
- Quality measure feedback reports should be simplified and standardized across all payers to make them more actionable.
- Quality measures should be updated regularly or when new evidence is developed.
- As new quality measures are adopted, sponsoring entities should sunset other quality measures.
- Physicians should not be accountable for quality measures that they do not have the control over nor authority to improve.

3. Certification and Documentation

Physicians want to efficiently order what their patients need to manage their disease conditions in a way that maintains their health. The current procedures surrounding coverage of medical supplies and services impede this goal and add no discernible value to the care of patients.

Principles:

- The physician's order should be sufficient. Physicians should not have to sign multiple forms from various outside entities for patients to receive needed physical therapy, home health, hospice, or Durable Medical Equipment (DME), including diabetic supplies.
- Physicians should not be required to recertify DME supplies annually for patients with chronic conditions.

- Authorization for supplies should be generic so that physicians are not required to fill out a new form every time a patient switches brands, including but not limited to diabetic supplies.
- Authorization forms should be universal across payers. Data within the forms should be standardized to allow for automated EHR extraction and population of forms.
- Physicians should not be required to attest to the patient's status when the service is provided by another licensed health professional as is the case with diabetic footwear.

4. Medical Record Documentation

Documentation burdens have increased dramatically, despite adoption of Electronic Health Records (EHRs). Documentation requirements for public and private payer programs and initiatives have escalated. Further, the Centers for Medicare and Medicaid Services (CMS) Documentation Guidelines for Evaluation and Management (E/M) Services, established 20 years ago, do little to support patient care, and serve more as a framework to help physicians justify their level of billing (e.g. level 3, 4, or 5) than to help physicians diagnose, manage, and treat patients. Adherence to the guidelines consumes a significant amount of physician time, and does not reflect the workflow of primary care physicians. The guidelines were drafted for use with paper-based medical records, and do not reflect the current use and further potential use of electronic health records and team-based care. The guidelines negatively impact the usability of EHR software programs.

Principles:

- As part of the Medicare Quality Payment Program, documentation guidelines for E/M codes 99211-99215 and 99201-99205 must be eliminated for primary care physicians.
- Changes must be made to the outdated E/M documentation guidelines and the Medicare Program Integrity Manual. The changes should include the acceptability of medical information entered by any care team member related to a patient's visit. This standard should be applied by all Medicare contractors, Medicaid, marketplace policies, and private payers.
- The primary purpose of medical record documentation should be to record essential elements of the patient encounter and communicate that information to other providers. The use of templated data and box-checking should be viewed as administrative work that does not contribute to the care and wellbeing of the patient.
- EHR vendors, physicians, and workflow engineers must collaborate to redesign and optimize EHR systems.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements

(1) Fraud Reduction Activities

Summary

CMS adopted the commercial Medical Loss Ratio (MLR) rules as a reference point for developing the Medicare MLR rules. Consistent with this alignment, the Medicare MLR regulations adopted the commercial MLR rules' exclusion of fraud prevention activities from Quality Improvement Activities (QIA). These rules were further aligned by allowing the amount of claim payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, to be included in the MLR numerator as an adjustment to incurred claims. CMS explained this approach was considered

because the recovery of paid fraudulent claims would reduce an MLR and create a disincentive to engage in fraud reduction efforts.

CMS proposes to change the Medicare MLR rules because they believe that limiting or excluding amounts invested in fraud reduction undermines the federal government's efforts to combat fraud in the Medicare program and reduces the potential savings to the government, taxpayers, and beneficiaries that robust fraud prevention efforts in the MA and Part D programs can provide. CMS proposes to expand the definition of QIA to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

AAFP Response
AAFP supports MLR requirements of Part C and D sponsors since it will help ensure that health care finances are focused on patient care rather than insurer profits. The AAFP also agrees with the CMS proposal to expand the definition of QIA to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

(2) Medication Therapy Management
Summary
Medication Therapy Management (MTM) is defined as a systematic process of collecting patient-specific information, assessing medication therapies to identify and prioritize medication-related problems, and creating a plan to resolve them. In the May 23, 2013 final rule, CMS stated that MTM activities qualified as QIA provided they meet certain requirements. CMS states in their prior MLR rulemaking, they did not determine whether all MTM programs that are compliant would be QIA. Consequently, CMS received numerous inquiries seeking clarifications regarding whether MTM programs are QIA.

CMS proposes to specify that all MTM programs that are compliant and offered by Part D sponsors (including MA organizations that offer MA-prescription drug plans) are QIA. CMS believes that allowing Part D sponsors to include compliant MTM programs as QIA in the calculation of the Medicare MLR would encourage sponsors to ensure that MTM is better utilized, particularly among standalone PDPs that may currently lack strong incentives to promote MTM. CMS further stated concerns that Part D sponsors may be restricting MTM eligibility criteria to limit the number of qualified enrollees, and they believe that explicitly including MTM program expenditures in the MLR numerator as QIA-related expenditures could provide an incentive to reduce any such restrictions.

AAFP Response
CMS stated in the proposed rule that beneficiaries with higher rates of medication adherence have better health outcomes, and that medication adherence can also produce medical spending offsets, which could lead to government and taxpayer savings in the trust fund, as well as beneficiary savings in the form of reduced premiums. The AAFP agrees with these CMS conclusions. However, a crucial element of medication adherence is access to a primary care physician.

Primary care and care coordination improve medication adherence and adherence to all treatment protocols. The AAFP's Standard Primary Care Benefit policy/proposal states in part, "It is well-recognized that the two most influential indicators of health are continuous health care insurance coverage and a usual source of care, typically through a continuous relationship with a primary care physician." The complexity of care provided by family physicians is unparalleled in medicine. Family physicians address more diagnoses and offer more treatment plans per visit than any other medical

specialty. Furthermore, according to a Scientifica article, The Impact of Primary Care: A Focused Review, the number and complexity of conditions, complaints, and diseases seen in primary care visits is far greater than those seen by any other physician specialty.

Again, the AAFP agrees with the CMS conclusion that medication adherence reduces costs to taxpayers and lowers premiums. However, for primary care physicians to provide coordinated, comprehensive care that aids in ensuring medication adherence, family physicians need to be paid appropriately. As payment moves to value-based care where providers are responsible for population health management, including medication management, and total cost of care, the AAFP believes increased investment in primary care is a necessity.

(3) Additional Technical Changes to Calculation of the Medical Loss Ratio
Summary
CMS states the forms used to report MA and Part D MLR data is substantially different than commercial forms. To reduce unnecessary burden, CMS proposes that the Medicare MLR reporting requirements would be limited to the organization name, contract number, adjusted MLR and remittance amount.

AAFP Response
The AAFP continues to support MLR requirements since it helps ensure that health care finances are focused on patient care rather than insurer profits. The AAFP appreciates these CMS efforts to decrease administrative burden. However, the AAFP is concerned that easing the reporting requirements may create an opportunity to falsely report MLR data. In the past, managed care plans have misclassified expenses to create the appearance of a higher medical loss ratio. The AAFP believes detailed reporting requirements are important to maintain MLR accuracy.

About Family Medicine
Family physicians are dedicated to treating the whole person. These residency-trained, family medicine specialists in primary care provide a wide variety of clinical services. They treat babies with ear infections, adolescents with depression, adults with hypertension, and seniors with multiple chronic illnesses. With a focus on prevention, primary care, and overall care coordination, they treat illnesses early and, when necessary, refer their patients to the right specialist and advocate for their care. One out of every five office visits in the United States are made with family physicians. More than 192 million office visits are made to family physicians each year. This is 66 million more than the next largest medical specialty. More Americans depend on family physicians than on any other medical specialty.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

John Meigs, Jr., MD, FAAFP
Board Chair