



May 9, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

Dear Acting Administrator Slavitt:

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I am responding to the [proposed rule](#) titled, "Medicare Program; Part B Drug Payment Model" as published by the Department of Health and Human Services (HHS) in the March 11, 2016, *Federal Register*. The Centers for Medicare & Medicaid Services (CMS) issued this proposed rule to discuss implementing and testing a new Medicare Part B drug payment model under section 1115A of the *Social Security Act* (the Act). The AAFP appreciates that CMS issued this proposed rule to make changes to the Act based on experience with the program and to respond to concerns raised by stakeholders about the escalating costs of prescription drugs, biologicals, and biosimilars ("drugs").

The transformation of our health care system requires fresh perspectives and new ideas on how we deliver and pay for health care services. The AAFP applauds CMS's efforts to apply common-sense, value-based payment (VBP) principles to the delivery of physician-administered pharmaceutical and biologic treatments. VBP involves linking payment for drugs to patient outcomes and cost-effectiveness rather than solely to the volume of sales. Physicians, hospitals, and other Medicare providers are aggressively pursuing VBP models, and it makes sense that we would explore the applicability of these same ideas to the pharmaceutical industry. The emergence of these VBP models, running concurrently with health care transformation, should create a collaborative environment between payers, providers, pharmaceutical manufacturers, and other stakeholders with the goal of creating opportunities to increase quality and access for patients and to improve their health. The current trajectory of health care costs requires we act now and test approaches for transitioning from a fee-for-service (FFS) and volume-based payment system to one that encourages physicians, providers, and suppliers to achieve better patient health or lower utilization and drug expenditures. By seeking public comment on how to test new payment models for physician-administered medications, CMS is taking a step toward ensuring that Medicare patients get the most appropriate drugs while simultaneously minimizing out-of-pocket costs for patients. The AAFP urges CMS to design this and other proposed VBP models in a way that preserves or even enhances the quality of care provided to Medicare beneficiaries by family physicians and other primary care providers. The AAFP believes the model should not result in patients receiving different standards of care based solely where they live or the type of setting in which care is provided. VBP for physician services and drug pricing will continue current efforts to hold the health care delivery system accountable for both quality and cost of care. Physicians are being asked to stand behind the

www.aafp.org

President Wanda Filer, MD York, PA	President-elect John Meigs, Jr., MD Brent, AL	Board Chair Robert L. Wergin, MD Millford, NE	Directors Yushu "Jack" Chou, MD, Baldwin Park, CA Robert A. Lee, MD, Johnston, IA Michael Munger, MD, Overland Park, KS Mott Blair, IV, MD, Wallace, NC John Cullen, MD, Valdez, AK Lynne Lillie, MD, Woodbury, MN	John Bender, MD, Fort Collins, CO Gary LeRoy, MD, Dayton, OH Carl Olden, MD, Yakima, WA Marie-Elizabeth Ramas, MD, (New Physician Member), Mount Shasta, CA Richard Bruno, MD, (Resident Member), Baltimore, MD Tiffany Ho (Student Member), Baltimore, MD
Speaker Javette C. Orgain, MD Chicago, IL	Vice Speaker Alan Schwartzstein, MD Oregon, WI	Executive Vice President Douglas E. Henley, MD Leawood, KS		

performance of their care and it seems appropriate to ask pharmaceutical manufacturers to stand behind the performance of their drugs.

VBP compensates family physicians for patient-centered care that improves health and holds them accountable for managing the total cost of care. Family physicians and other primary care providers can be responsible for managing the total cost of care, but currently they are unable to influence or control health care or drug costs. Patient choice, adherence, and accountability affect the total cost of care and should be quantified and factored into VBP calculations. Depending on the insurance product, patients are able to choose which services to utilize even if their family physician does not recommend those services. In addition, patients may choose to see providers outside their network. Also within VBP, performance measurement attempts to assess the effectiveness and efficiency of care delivered to patients. However, patient adherence affects the care delivered when patients either do not listen to the advice of their physician or are unable to follow a treatment plan recommended by their physician and it can ultimately alter a physician's performance score. For example, patients may believe they do not need an inexpensive cholesterol medication, and other patients may not be able to afford the diabetes medication their physician prescribes for them. Therefore, physicians should not be responsible for costs they do not control, and physician accountability for costs needs to be balanced with patient accountability.

Proposed Rule Section II. B. Proposed Drugs Paid under Part B to Be Included in the Model

CMS proposes to include all Part B drugs in this model, with limited exceptions. The AAFP hears from members that current vaccine payments do not cover the cost of administering vaccines. As a consequence, some family physicians have had to quit administering vaccines. In addition, members have reported financial difficulties in meeting the regulations for cold handling, special packaging, and appropriate disposal of vaccines. The AAFP strongly urges CMS to consider including vaccines in this model and to create a separate payment proposal that would encourage more primary care physicians to offer vaccines in their practices, at the point of care.

Proposed Rule Section II. C. Proposed Participants, Selected Geographic Areas, and Sampling

CMS proposes to require all providers and suppliers in selected geographic areas who are furnishing and receiving payment for the drugs separately paid under Part B be included in this proposed model. In Phase II, CMS will include the majority of drugs paid under Part B and will randomly assign providers and suppliers within a defined primary care service area to one of these groups:

1. Group earning a modified average sales price (ASP) add-on amount
2. Group implementing VBP tools
3. Group earning a modified ASP add-on and implementing VBP tools at the same time
4. Group neither earning a modified ASP nor implementing VBP tools (control group)

The AAFP understands the statement that CMS is "not proposing a reduction to total spending for Part B drugs," but rather is attempting "to test redistribution of the add-on payment on Part B drugs expenditure and outcomes." In 2015, the AAFP and Humana conducted a [survey](#) of family physicians to understand their perceptions and attitudes on VBP. The survey showed practice sustainability was the factor that 92 percent of family physicians felt was most important in evaluating the success of a

VBP program. This model needs to be designed in a way that provides an opportunity for practices of different sizes and levels of sophistication to succeed and accurately predict the potential effects among a large array of practice-types. In addition, physicians participating in this model need the tools and resources to be successful and to preserve or enhance the quality of care provided to Medicare beneficiaries, while simultaneously minimizing costs.

Proposed Rule Section III. A. 1. Methodology for Creating Modeling Data Set

CMS proposes to use calendar year (CY) 2014 utilization for drugs paid under Part B to calculate the amount of payments that were associated with the 6 percent ASP add-on percentage. The AAFP recognizes more CY 2014 claims data would be available due to additional claims processing, which CMS would include in modeling the final rule. However, the AAFP would urge CMS to use the CY 2015 claims data set, updated as of March 2016, to confirm and validate calculations, which are based on CY 2014 claims, for the flat fee amount in the final rule.

Proposed Rule Section III. A. 2. Add-on Proposal: Percentage Plus a Flat Fee

CMS proposes to change the add-on amount from a percentage that applies in all circumstances to a lower percentage (2.5 percent) plus a flat fee (\$16.80 per drug, per day administered). The flat fee would be annually updated by the percentage increase in the consumer price index for medical care for the most recent 12-month period. The AAFP believes that appropriate steps should be taken to address rising drug costs and to reform the current payment system for drugs. The current system does not vary the ASP payment amount based on the price an individual physician or supplier pays to acquire the drug. This oversight puts solo and small practices at an economic disadvantage and does not accurately calculate the real ASP of drugs. Furthermore, payment determinations do not take into account the performance or value of a particular drug or the cost of clinically comparable drugs that may be priced exclusively in other Healthcare Common Procedure Coding System codes. This methodology enables expensive drugs to receive higher add-on payment amounts, compared to inexpensive drugs, regardless of their value. Finally, the AAFP sympathizes with CMS' concern about the potentially large boost the flat fee could produce for inexpensive drugs. In the spirit of simplifying this part of the model, the AAFP suggests using a threshold level below which no flat fee would be added and above which physicians would receive the full \$16.80. For example, if the ASP plus the 2.5 percent add-on is less than \$16.80, then no flat fee would be added. Therefore, the flat fee would never equal or exceed 100 percent of ASP plus the 2.5 percent add-on.

Also within the current volume-based payment system for drugs, primary care practices have come to rely on the 6 percent add-on as revenue needed to purchase, store, and dispense drugs. Depending on the size and levels of sophistication and integration of a practice, a reduction to the add-on could prove difficult to mitigate. A large practice or health system can often meet regulatory requirements for cold handling, special packaging, and the proper disposal of drugs; those overhead costs are spread across the financial operations of the system. However, solo-practice physicians or physicians in a small practice would have a hard time covering those costs. In addition, they would be at the mercy of additional distribution mark-ups that would have been paid for by the manufacturer-reported ASP and the 6 percent add-on. Even though there is no documented reason for the 6 percent add-on to the ASP, primary care practices have come to depend on that payment in their operations and accounting. If CMS chooses to proceed with a lower add-on percentage plus a flat fee, we call on

CMS to provide a timely feedback mechanism for physicians, providers, and suppliers to notify CMS if the add-on percentage or flat fee is not reasonably set to cover handling, overhead, and markups from wholesalers and distributors. CMS needs to monitor and to quickly intervene if the costs of purchasing, storing, and dispensing drugs become unmanageable in this model. In other words, the add-on percentage and flat fee should be fair and flexible.

Additionally, the AAFP strongly opposes CMS' proposal to require the use of a G code to claim the flat fee. CMS would already know which physicians use G codes, based on their ZIP codes, as compared to the ZIP codes in the affected Primary Care Service Area. In addition, if physicians are required to use G codes, the model may not be budget-neutral because many physicians may neglect to include the G code. The AAFP does not understand why CMS would make the physician take the extra step of filing a G code to claim the flat fee. **The AAFP would urge CMS to add the G code automatically, where appropriate, to provide administrative simplification for physicians.**

Proposed Rule Section III. A. 3. Comment Solicitation: Additional Tests of Add-on Modifications

CMS mentioned a June 2015 Medicare Payment Advisory Commission (MedPAC) [report](#) detailing a lower add-on percentage plus a flat fee and predicted how the new model would redistribute payment for a primary care physician and a rheumatologist. Redistribution under this approach favors provider specialties and suppliers that utilize relatively inexpensive drugs. The MedPAC report determined that under this approach physician specialties that heavily utilize drug therapies would see a decrease in drug revenues while specialties that utilize fewer drugs, like primary care, would see an increase in drug revenue. While the AAFP does not challenge the findings of this report, we are concerned with the primary focus on costs, rather than outcomes or quality. Payment determinations for physician services or drugs should first take into account outcomes, quality, and patient experience, before taking into account cost savings.

The AAFP also encourages CMS to explore using a variety of add-on percentages or flat fees across several tiers of drugs, based not solely on costs, but also on performance. Value-based pricing of prescription drugs, using an ASP, add-on, or flat fee should take a balanced approach using factors such as research and development costs, clinical outcomes/efficacy, clinical comparability, side effects, safety, patient adherence, and patient ease of use. In addition, this approach should not create separate pay-for-value structures for each new drug, but rather a practical, pay-for-value structure for most drugs. The AAFP offers this basic framework for value-based pricing of prescription drugs:

- A drug with proven, positive clinical outcomes has value.
- A drug without proven, positive clinical outcomes does not have value.
- A high-cost drug still has value if it improves a patient's health and reduces spending on other forms of health care.
- If a new drug has the same clinical outcome as an older drug, the two have equal value.

Savings generated through value-based pricing should be passed through to patients, as well as payers, pharmaceutical manufacturers, and other stakeholders.

We note the inherent conundrum of trying to fix a volume-based payment system with modifications and adjustments. It did not work in FFS, and it will not work long-term for drugs. A lower add-on percentage with a flat fee may potentially increase the risk of having payment fall below acquisition and dispensing costs for certain drugs, particularly for physicians and suppliers whose acquisition costs are near or above a drug's ASP.

While the AAFP is not arguing against changing the ASP add-on payment methodology, we offer an alternative payment model for the ASP. The ASP should be calculated prospectively, based on current and past market trends, along with current and past utilization trends, using manufacturer-submitted data on sales to all purchasers with manufacturers' rebates, discounts, and price concessions, and updated monthly, rather than quarterly. This will help predict expected price variations among drugs and decrease the risk for underpayment to practices.

Proposed Rule Section III. B. 2. Value-Based Pricing Strategies

CMS proposes value-based pricing strategies that include one or more of the following specific tools: reference pricing, indications-based pricing, outcomes-based risk-sharing agreements, and discounting or eliminating patient coinsurance. On reference pricing specifically, CMS proposes to not allow for balance billing of the beneficiary for any differences in drug pricing. CMS will group similar drugs into a single payment rate in order to give prescribers incentives to use the drug product that provides the most value for the patient. The AAFP urges CMS to construct drug groupings based not only on costs, but also on a comprehensive performance analysis using criteria like clinical outcomes/efficacy, clinical comparability, side effects, safety, patient adherence, and patient ease of use. Reference pricing should make it easy for physicians to judge the therapeutic- and cost-effectiveness of drugs, within a disease group, and be properly reimbursed for prescribing them.

The AAFP stresses that primary care is more clinically nuanced than other specialties. The [concept](#) of "clinical nuance" illustrates two important facts about primary care; first, services rendered to patients differ in their outcomes and second, the clinical benefit derived from a medical service depends on who is using it, who is delivering the service, and where it is being delivered. Primary care physicians treat as many as 2,500 patients on their panels, and each patient has varying acute conditions, chronic conditions, and adherence levels. These primary care physicians have meaningful, continuous, and longitudinal relationships with their patients and, therefore, know best how to treat them. In addition, the AAFP has a [policy](#) on "Patient-Centered Formularies" which states, "Formularies should be designed to offer patients multiple levels of drug choice (from more to less restrictive) with accompanying patient cost sharing levels to account for variables including patient preferences." The policy goes on to say, "Formularies should restrict as few classes of therapeutic agents as possible, focusing on those classes of drugs that are the most frequently prescribed, the most expensive, or the most frequently 'abused,' i.e., to seek value in selected therapeutic categories." Drug groupings and reference pricing should not restrain primary care physicians from delivering high-quality care.

Since family physicians do not have total control over costs, or their patients, for that matter, fair and effective accountability should take this into account. For patients who want the more expensive drug, they should be able to pay the difference between the cost of those drugs and the lower reimbursement. The AAFP would ask CMS to consider allowing balance billing with a signed Medicare Advance Beneficiary Notice to indicate the patient understands the consequences of this

decision. It is a fact of life that some patients either do not listen to the advice of their physician or are unable to follow a treatment plan their physician recommends. Therefore, physicians should not be responsible for costs they do not control, and provider accountability for costs needs to be balanced with patient accountability.

On indications-based pricing specifically, CMS proposes to use a value-based pricing strategy that would vary prices for a given drug based on its clinical effectiveness for different indications that are covered under Medicare. The AAFP believes value-based or, in this case, indications-based pricing of drugs should take a balanced approach using factors such as research and development costs, clinical outcomes/efficacy, clinical comparability, side effects, safety, patient adherence, and ease of use for the patient. In addition, this approach should not create separate pay-for-value structures for each drug, but rather a practical, pay-for-value structure for most drugs. The AAFP offers this basic framework for value-based pricing of prescription drugs:

- A drug with proven, positive clinical outcomes has value.
- A drug without proven, positive clinical outcomes does not have value.
- A high-cost drug still has value if it improves a patient's health and reduces spending on other forms of health care.
- If a new drug has the same clinical outcome as an older drug, the two have equal value.

Indications-based pricing should be supported by evidenced-based clinical practice guidelines and published studies or reviews to align drug payment with outcomes for a particular clinical indication. The drug information used to set indications-based prices should include a complete comparative- and cost-effectiveness analysis during clinical phases, when the drug is evaluated by the Food and Drug Administration, and during patient utilization, when the drug is approved for sale. Focusing on outcomes will require drugs to perform in the real world as well as they did during clinical phases. Naturally, information from independent and neutral sources should be used in conjunction with information from pharmaceutical manufacturers to ensure valid, reliable, and scientific evidence generalizable to the Medicare population. Indications-based pricing should be fair and flexible.

On outcomes-based, risk-sharing agreements specifically, CMS proposes that pharmaceutical manufacturers provide performance measures to determine the clinical value for a specific drug in outcomes-based, risk-sharing agreement. The AAFP believes this proposal should include details on the scope of CMS' authority, a clearly defined objective, and the mechanism for negotiating outcomes-based, risk-sharing agreements. CMS needs to specify several important considerations, such as what is being negotiated, (prices, formulary placement, or both), and what to do if the negotiating parties are unable to come to agreement. A pricing framework, similar to the one offered above, to guide arbitration in determining the price of drugs is also needed to capture the relevant factors that would be considered in determining the appropriate price for a drug.

The AAFP notes private payers are entering into voluntary agreements with pharmaceutical manufacturers that link clinical outcomes with payment. In February 2016, for example, Cigna entered into an outcomes-based contract with Novartis for the drug Entresto to treat patients suffering from heart failure. The pay-for-performance agreement ties the payment to how well the drug improves the relative health of Cigna's members. The primary metric is reduction in the proportion of patients with heart-failure hospitalizations. In November 2015, Harvard Pilgrim Health Care reached a pay-for-performance deal to cover Amgen's cholesterol medicine, Repatha. Under the deal, Harvard Pilgrim will receive the drug at a discount and Amgen agreed to provide larger rebates to the insurer if

Repatha does not lower patients' low-density lipoprotein cholesterol to levels observed in clinical trials and if the medication is used more than a set amount. These types of payer/pharmaceutical agreements, along with many more, will help to establish a drug's long-term value with regard to the magnitude of patient health outcomes.

Also on outcomes-based risk-sharing agreements, CMS seeks comments on methods to collect and measure outcomes, including parameters around standardizing value metrics based on differences in drug treatments and their targeted patient subpopulations. In general, value can be measured using quality, clinical outcome, utilization, cost, and patient experience metrics. Specifically, for outcomes-based, risk-sharing agreements on drugs, performance measurement should take the same balanced approach. Drug performance measurement could take into account factors such as research and development costs, clinical outcomes/efficacy, clinical comparability, side effects, safety, patient adherence, and patient ease of use. We believe CMS should harmonize drug performance measures in the same way it harmonized physician performance measures. It is important for CMS to create a collaborative environment between payers, physicians, pharmaceutical manufacturers, and other stakeholders with the goal of creating opportunities to increase quality and access for patients, and improve their health. Anthem and Eli Lilly and Company, for example, are collaborating to help accelerate the transition towards a value-based system with [policy proposals](#) that will help drive VBP innovation. Both companies believe that "to design a contract that makes payment for a therapy contingent on patient outcomes... the manufacturer and the health plan must agree on how to reliably, accurately, and appropriately measure outcomes and categorize patients as 'responders' or 'non-responders.' In addition, both plans and manufacturers need to designate staff to monitor and execute the agreement, a further investment by both parties." Furthermore, the data on prescription drugs needs to include a complete comparative- and cost-effectiveness analysis during clinical phases, when the drug is evaluated by the Food and Drug Administration, and during patient utilization, when the drug has been approved for sale. Focusing on outcomes will require prescription drugs to perform in the real world as well as they did during clinical phases.

Finally, the shift to value-based care and payment will require a higher level of collaboration and trust from physicians, payers, purchasers, and patients that will only come from increased transparency. Physicians, payers, and pharmaceutical manufacturers should work together in the performance measure development process. Additionally, the AAFP believes payers need to define and disclose the measures and methodologies for physician and drug performance. Physicians and pharmaceutical manufacturers must know how they will be measured and how they can succeed in value-based arrangements. In addition, clinical and cost information on physician performance for referrals and on drug performance for prescribing needs to be transparent. The AAFP believes patents awarded to pharmaceutical manufacturers provide sufficient protections on proprietary information for manufacturers to develop, market, and eventually profit from their drugs. Since pharmaceutical manufacturers apply for patent protection well before clinical phases and the protections last about twenty years in the United States, the effective patient protection period is often around seven to twelve years after the drug has received approval. The AAFP urges CMS not to let the needs of protecting proprietary information of a select few stakeholders derail the shift towards a transparent, fair, and improved health care system for all.

On patient coinsurance amounts specifically, CMS proposes to discount or eliminate the beneficiary coinsurance amounts, currently 20 percent, for services that are determined to be high in value. The AAFP applauds CMS for this proposal and supports the notion of holding the prescribing physician harmless in the drug payment calculation. We believe CMS and private payers should eliminate

coinsurance on certain drugs and physician services to increase access to care and reduce administrative burdens on practices bearing the cost of collecting coinsurance. The has a [policy](#) on “Value-Based Insurance Design” (VBID) which states, “The primary objective of VBID is to reduce and eventually eliminate financial barriers to high-value health care services.” We believe VBID to be extremely important for patients, with long-neglected ailments, who cannot afford the drugs and services they need. VBID for primary care would provide an appropriate incentive to beneficiaries to use preventive care and chronic disease management for early diagnosis and treatment of acute conditions offered by family physicians and other primary care providers. Moreover, the AAFP’s [policy](#) on “Health Care for All,” which advocates that primary care is provided through the Patient-Centered Medical Home and that patients should have no financial barriers, such as coinsurance, that might impede access to their family physician. Naturally, the AAFP believes the proper design and implementation of VBID will reduce the burdens of cost-sharing for certain physician services and drugs seniors need and will increase the use of high-value physicians and drugs.

Proposed Rule Section III. B. 3. Development of a Clinical Decision Support Tool

CMS proposes to implement a clinical decision support (CDS) tool for physicians prescribing appropriate drugs. The tool would have two components consisting of an online interface that supports clinical decisions through education and a feedback mechanism based on drug utilization in Medicare. The AAFP applauds CMS for developing and implementing such a tool; physicians need the drug performance data to make informed, value-based decisions on prescribing drugs, along with evaluating and managing therapies. The AAFP [policy](#) on “Patient-Centered Formularies” states, “Health plans and [pharmacy benefit managers] should provide drug utilization and cost information to physicians in clear and understandable reports that are useful for physicians in affecting positive change in their prescribing behavior.” As value-based arrangements tie payment to physicians’ performance, physicians’ performance will then be bound to prescription drug performance. Therefore, family physicians and other primary care providers need clear, real-time, patient-specific information to make the best care decisions for their patients. Clinical and cost information on drugs should include:

- Clinical outcomes
- Drug interaction and allergy alerts along with clinical support guidelines
- The patient’s demographic information
- The patient’s prescription drug benefit coverage
- The out-of-pocket costs the patient will incur at any given pharmacy for prescribed medications (along with alternative pharmacy options)
- Alternative drug therapies for a physician’s consideration

The AAFP believes CDS tools should help physicians and their care teams proactively identify the best treatment option, early warnings of potential problems, and alternative treatments for the physician, care team and patient to consider. The CDS tool should contain drug information based on evidence-based, up-to-date, scientific/medical evidence that is a mixture of clinical information, such as updated guidelines for the clinical use of drugs, updated safety information, and processed patient data, that takes into account their experiences and outcomes. Only with this complete dataset will the CDS tool enable physicians to ensure the correct drug dosing, reduce the risk of toxic drug levels, reduce the time to achieve therapeutic drug levels, decrease medication errors, and change prescribing patterns in accordance with evidence-based clinical guidelines. Without the free flow of bi-

directional information from all stakeholders working together to get people healthy, the notion of value-based health care will never materialize.

However, CDS tools should not act as, interfere with, or replace, in any way, the physician's medical judgment for the treatment of patient-specific clinical conditions. Our [policy](#) on "Generic Drugs" states, "The AAFP maintains that the family physician is the patient's advocate. That advocacy demands that the family physician prescribe safe, efficacious pharmaceutical products to deliver high quality medical care, with sensitivity to the patient's individual medical and financial circumstances."

CMS stated "Medicare Part D plans, PBMs, other third party payers, and entities like hospitals use a variety of... clinical decision support tools... to improve patient outcomes and manage drug costs discounts and rebates" and "Based on background work done on this model, we believe private payers are currently using these tools to manage drugs under a medical benefit." The AAFP disagrees. While these and other tools exist to manage drug costs, they do not provide complete information, such as clinical outcomes, to physicians at the point of care. For example, DrFirst, a vendor of e-medication management software and services, recently launched its new [myBenefitCheck](#) service, which offers real-time, patient-specific information to physician practices regarding a patient's insurance benefit and drug options. Even though this service helps physicians manage a prescription drug benefit by commercial health plans, PBMs, and other entities that manage health benefits and drug utilization, it does not provide clinical information on quality or outcomes. Many of our members reported being able to use their electronic health record only as a formulary checker, with inaccurate results at best. These family physicians have resorted to using Costco's [Drug Directory](#) that has up-to-date pricing details and general information on drugs. It is ironic to name a tool "clinical decision support" when there is precious little clinical information in the tool to support health care decisions. To successfully manage and improve a patient's health, physicians need a drug's performance on quality and outcomes just as much as they need its cost. Therefore, the AAFP calls on CMS to include drugs' clinical performance data in the CDS tool before implementing and testing this model. In addition, because physicians will come to rely heavily on this tool to make value-based prescribing decisions, the AAFP hopes the contractor CMS is using to develop the CDS tool has solicited feedback from physicians and implemented necessary enhancements to ensure the CDS tool is useful and user-friendly. The AAFP also hopes CMS and the contractor have field-tested the CDS tool among practices and health systems; we would be very interested in knowing physicians' initial perceptions of the CDS tool.

CMS also stated the CDS tool "could provide feedback on how an individual physician's drug claim patterns compare with local or national data or even recommended guidelines." The AAFP seeks to provide family physicians with learning opportunities that improve their competence, support their performance and preparedness for certification and licensure, and increase the vitality and efficiency of their practice. In addition, our continuing medical education/continuing professional development (CME/CPD) activities are designed to facilitate changes in physicians' knowledge, competence, and performance. We support CMS' goal of using the CDS tool as a mechanism to provide individual feedback, education, and data on the physician's prescribing patterns and resource use. However, the CDS tool should objectively illustrate a physician's practice patterns and provide evidence-based alternatives for improving these practice patterns. This information should be used solely for feedback and education to support a physician's interest in mindful prescribing.

Lastly, it would seem the CDS tool for reporting feedback on a physician's pattern of drug claims may be similar to an established process for providing physician's quality and resources use reports

(QRURs). If so, this could pose a challenge, given how much trouble physicians have learning about and accessing their QRURs. Most physicians are unaware of the report's existence, let alone the importance of the information contained within it. Additionally, the tables and calculations contained in the report can be difficult to interpret, let alone act on. Therefore, with the CDS tool, the AAFP urges CMS to ensure physicians are aware of the tool and to make the tool easy to access and interpret. The AAFP also urges CMS to provide technical assistance to practices to better understand the drug claims pattern data and how that data will impact their Medicare payment.

Proposed Rule Section III. D. Interactions with Other Payment Provisions

CMS proposes to not exclude beneficiaries, physicians, suppliers, and other providers in this proposed model from other Center for Medicare and Medicaid Innovation (CMMI) payment models, such as the Medicare Shared Savings Program (MSSP) and the Bundled Payments for Care Improvement initiative. The AAFP is concerned with the potential overlap between this proposed model and other CMMI payment models causing change fatigue among physicians and other providers. CMS believes this model will typically affect a small proportion of the beneficiary's total payments for care for those assigned to practices in the MSSP. However, we urge CMS to look at the totality of change coming to the health care system, especially for physicians and other providers, and the speed at which this changing is coming. Patients should not feel the difference if they are cared under a properly designed and executed value-based arrangement—except for getting healthier. Physicians and other providers are the ones who will manage and make the changes needed to provide value-based care. Excluding practices already participating in other payment models from this proposed model may not be the best solution because some may have the capabilities and willingness to participate in this model. **The AAFP would urge CMS to consider delaying this model until 2018, so CMS can receive additional feedback on the proposed rule and the potential overlap between various CMMI models.** If CMS chooses not to delay the deployment of this model, the AAFP calls on CMS to prevent duplication of model assignments, as best as it can, for practicing physicians.

Section VI. Evaluation

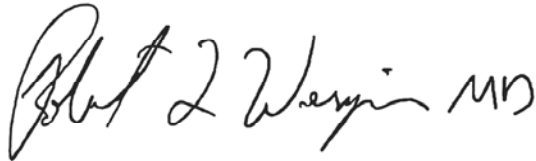
CMS proposes to evaluate the impacts of this model by comparing current and historic patterns of Part B drug use, program costs, clinical outcomes, and the quality of care for providers, suppliers, and beneficiaries. The AAFP is concerned CMS will base too much of its analysis on secondary data sources, such as Medicare FFS claims, that will shed light on only the costs of drugs. Just as physicians need drug performance data to make informed, value-based decisions on prescribing drugs, CMS also needs this data to effectively and completely evaluate this model. Not only does CMS need to obtain information that is representative of a wide and diverse group of stakeholders, including patients, it needs information that is representative of the true value of drugs. **Therefore, the AAFP advocates to CMS to develop a scalable and interoperable health information technology infrastructure to merge clinical and claims data from every stakeholder.** A complete picture of a drug's value, based on clinical and cost information, will best inform CMS on how such a VBP model might function if it were fully integrated into the Medicare program.

The AAFP believes a properly designed and executed VBP model for drugs can flourish and make the health care delivery system more accountable. We remain committed to working with CMS on

Acting Administrator Slavitt
Page 11 of 11
May 9, 2016

efforts that focus on better health care, better health, and lower costs. We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have. Please contact Milack Talia, Practice Environment Manager, at (913) 906-6000 extension 4175 or mtalia@aafp.org.

Sincerely,

A handwritten signature in black ink that reads "Robert L. Wergin MD". The signature is written in a cursive, flowing style.

Robert L. Wergin, MD, FAAFP
Board Chair