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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: *Medicare Program; Part B Drug Payment Model; CMS-1670-P*

Dear Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments on the *Medicare Program: Part B Drug Payment Model*. The AMA strongly supports efforts to investigate and control the escalating cost of prescription and Part B covered drugs and biologicals. The Centers for Medicare & Medicaid Services (CMS) is proposing to implement a two-phase, multipronged nationwide model that would restructure the way Medicare reimburses physicians for Part B drugs. However, we urge CMS to withdraw the proposed phase 1 of the current model and would welcome the opportunity to work collaboratively with the Agency to develop appropriately designed and scaled value-based models as part of new proposed §1115A models in order to improve patient care while also addressing overall health care costs.

As a threshold matter, we are concerned that the cuts proposed in phase 1 of the model could undermine Medicare beneficiaries' access to care from their established physician in their local community and move their treatment to higher cost delivery sites depending on where they live. This disruption to established care delivery will fall most heavily on medically complex, high acuity patients and small physician practices, particularly those in geographically isolated and remote areas of the country. Phase 1 of the model will not reduce the high cost of Part B drugs, but it does seem likely to increase, rather than reduce, Medicare expenditures and patient cost-sharing. It also would divert attention from more targeted approaches that CMS should consider.

In light of the foregoing, the AMA strongly urges CMS to:

- Allow the Government Accountability Office (GAO) to complete its report examining how Medicare's payment for drugs covered under Medicare Part B compares to providers' actual acquisition and overhead costs before implementing new test model(s).
- Rescind the current proposed rule model.
- Consistent with the Agency's §1115A test model authority, undertake interactive consultations with clinical and analytical experts with expertise in medicine and health care management which

should include, but not be limited to, a town hall, or comparable engagement, to develop several new models that build off a number of current proposed phase 2 value-based options.

- Issue a new proposed model that comports with an appropriately modified scale, scope, and consultative process as Congress contemplated for §1115A phase 1 models that leverage information gathered by the Agency on the value-based options outlined in the proposed model's phase 2, including risk sharing agreements based on outcomes, evidenced-based clinical decision support, and targeted reduction or elimination of copays.
- Ensure the implementation of new proposed model(s) account for reasonable lead time and resources needed to integrate the model into practice, have clearly articulated and sound evaluation methods (particularly those that would meaningfully measure health outcomes and quality), and appropriate oversight and patient protections.
- Exclude other demonstration or pilot programs from the future, proposed model(s) to avoid specious correlations and undermine validity of findings.
- Include in the new proposed model an impact assessment of the Medicare Access and CHIP Reauthorization Act (MACRA) and the Protecting Access to Medicare Act (PAMA) on the ability of physician practices to implement the test model at the same time.

The foregoing recommendations are designed to minimize interruption to existing patient plans of treatment, enable sufficient time to implement, and enhance the reliability and validity of the eventual findings.

OVERVIEW OF KEY POINTS

Phase 1 and phase 2 of the model as currently fashioned have scientific, procedural, and clinical shortcomings. Most concerning, the overriding impact of phase 1 has the potential for widespread patient harm with nominal provisions to mitigate or address such harm during the pendency of the model. The following summarizes key concerns:

- Phase 1 of the model does not address the underlying causes or reduce the high cost of Part B drugs.
- Phase 1 of the model will increase costs to the health care system by moving care to higher cost sites of care.
- The proposed test model design is not scientifically sound, because it does not meet accepted standards for testing and evaluating health services and clinical interventions.
- The proposed test model is mandatory for beneficiaries yet lacks appropriate controls to minimize or mitigate harm to patients.
- The proposed payment test model exceeds CMS' §1115A waiver authority and does not comply with the statutory requirements that include analysis and findings of results from phase 1 serving as a basis for expansion nationally in phase 2.
- The proposed implementation timeframe is unworkable for phase 1 and phase 2 even if the scope and methods of the model were appropriate.
- The complexity of phase 1 and phase 2 combinations will create confusion and will detract scarce resources from physician practices that are implementing new MACRA and PAMA delivery reform and reporting requirements.

- The reimbursement cuts to targeted therapies, some of the steepest payment cuts in phase 1, when coupled with a couple of the phase 2 strategies, if not properly constructed, have the potential to disproportionately negatively impact personalized medicine and by extension the President's Precision Medicine Initiative and the National Cancer Moonshot initiative.
- The imposition of two phases for the test model with permutations that include overlap with other demonstration and pilot projects adds a staggering level of complexity that will confound findings of what should more accurately be characterized as hundreds of test models.

In sum, the AMA strongly urges the Administration to focus on the causes of high drug prices which, though multifactorial and complicated, are less complex and offer a more direct approach to address the problem, rather than this proposed Part B model that focuses instead on the physicians who must purchase these drugs. Solutions to these escalating prices should entail in the short-term remedying the market failures and/or removing barriers that have limited competition such as lengthy regulatory approvals for generic drugs and slow implementation of the biosimilar approval pathway.[1] Longer term, all stakeholders should be engaged in evaluating the value of transparency and measures that strengthen the quality of information about what is driving the higher prices and government bargaining strategies that would reduce such prices.

DISCUSSION

In general, Medicare reimburses physicians and hospitals for the cost of Part B drugs at a rate tied to the average sales price (ASP) for all purchasers—including those that receive large discounts for prompt payment and high volume purchases—plus a percentage of the ASP. Currently the percentage add-on is six percent, which is then reduced to 4.3 percent under the budget sequester enacted in 2011.

The Agency has proposed a Part B drug payment model with two phases and multiple arms. Under phase 1 of the model, CMS would retain the current rates in some communities and set a reduced rate of ASP+2.5 percent in addition to a $16.80 flat fee in others. After the sequester is factored in, the add-on in the model areas would be 0.86 percent of ASP plus $16.53. In phase 2, five additional "value-based" drug payment strategies (test arms) are on tap for implementation in specified localities next year or later. As a result, Medicare payment policy would remain unchanged in approximately 25 percent of the country while multiple changes could be applied to 75 percent of the country.

The Agency states that the proposal is budget neutral and in general would transfer Medicare revenues from specialties that administer very expensive drugs to those that provide less expensive drugs. The Medicare add-on for a drug purchased for $10 would rise from 43 cents today to $16.62 or 166 percent of ASP under the demonstration rate, while the add-on for a drug purchased for $2000 would drop from $86 to $33.73 or 1.7 percent of ASP. As a percentage of total Medicare revenues, CMS' biggest projected losers include rheumatologists, ophthalmologists, oncologists and hematologists. Oncology drugs account for approximately 40 percent of Part B drug expenditures. Specialties projected to benefit from the changes include primary care, orthopaedic surgery, infectious disease, and pain medicine.

Phase 2 of the model includes a range of additional possible drug payment strategies, as discussed below, but none of the proposed options contain sufficient detail or information on the evaluation criteria and

[1] In general, the most expensive Part B drugs are biologicals.

methods to measure improved patient health outcomes and quality specifically. This is concerning as CMS has indicated it will not issue another proposed rule even though the model's method and design do not include basic information on phase 1 and phase 2 that can be vetted by stakeholders as contemplated under §1115A model authority. While the Agency indicates that these models would be designed to promote integrity, transparency, and accountability, the process for developing and implementing will fall short of these stated aspirations if further dialogue with physicians and other impacted stakeholders is not built into the process before new models are implemented.

Proposed Test Model Does Not Address Causes of Drug Price Escalation

Although the AMA shares the Administration's concern that rising drug costs could make life-extending therapies unavailable to a growing number of patients, CMS' assumption that this problem can be solved by reducing Medicare reimbursement to physicians who purchase and administer those drugs and who have no influence over drug prices is misleading. Neither physicians nor their patients manufacture, distribute, market, or establish prices for Part B drugs. The Agency acknowledges that the phase 1 proposal only addresses the add-on amount to the manufacturer's ASP and does not directly address the manufacturer's sale price "which is a more significant driver of drug expenditures than the add-on payment amount for Part B drugs."

The add-on that CMS proposes to reduce to 0.86 percent accounts for several factors including the fact that the actual acquisition cost for physician practices can exceed ASP because their relatively smaller size and volume means that they are not able to negotiate large discounts and rebates. (ASP is after all a volume weighted <u>average</u> net of price concessions such as volume discounts, prompt pay discounts, cash discounts, and rebates.) Second, it is also widely understood that the add-on is used to defer the costs due to administrative complexity, overhead costs, and in the context of biologicals and biosimilars the additional costs associated with specialized shipment, storage, handling, and preparation.

Furthermore, phase 1 is based on a specious premise—i.e., that physicians may choose their patients' drug therapy based on the drug with the highest reimbursement to the physician. Although the Agency primarily relies upon a June 2015 Medicare Payment Advisory Commission (MedPAC) report to Congress to support this assertion, the reality is that MedPAC looked at that question and concluded that there is little evidence to support this claim. CMS also cannot offer evidence of significant, systemic abuse and as noted in recent MedPAC discussions, many factors other than reimbursement drive physician drug choice related to patient-centered considerations.

Just as in the Part D program where substitution to generic alternatives happens rapidly, so too a similar phenomenon occurs in Part B—which belies the assertion that physicians are incentivized by the larger add-on of a higher price drug. Furthermore, there are clear examples where use of higher cost therapies is driven by indication and clinical evidence, adverse drug reaction profile, and patient characteristics. For instance, use of Abraxane (branded nano-particle albumin-bound paclitaxel with its reported greater tolerance than paclitaxel) is relatively low in breast and lung cancer where other options are considered first-line. In contrast, the utilization in pancreatic cancer, where evidence clearly has demonstrated its effectiveness and tolerability which differentiates the product from its generic, is relatively high. This is true despite the fact that once a generic has been on the market long enough to drive down the ASP (which is a blend of the generic and name-brand drug ASP), the physicians who use the brand-named drug are financially penalized given the higher acquisition cost of the brand drug relative to the generic.

One study relied upon by MedPAC, the Jacobsen study, attributes increased use of a more expensive lung cancer drug to changes in Medicare drug payment rules, but fails to mention that over the time in question, clinical evidence began to favor the more expensive drug thereby leading to appropriate change in drug therapies for these patients. The clinical reality is that opportunities to select therapies based on drug costs and reimbursement are very limited, either because a patient's condition or response often dictates use of a particular drug, or because each of the options will eventually be needed to the extent the patient's condition progresses. For example, in the oncology setting, the appropriate drug regimen for a particular patient depends not just on the type and origin tissue of the cancer but on the stage, the patient's condition and comorbid features, the molecular variants driving tumor growth, and many other variables. Given these many variables, some drugs may be appropriate and some may be ruled out. Some are given together, and some are given sequentially—as the efficacy of the first choice of drug wanes, a second and then potentially a third will be used. In these cases, the model will penalize physicians for selecting a more expensive drug even if it is the only appropriate drug for their patient.

The heart of the problem is drug prices. Manufacturers control prices, not physicians. Under phase 1 of the proposed model, CMS assumes that physicians who could not purchase the most effective drug at or below Medicare's new payment rate would either go back and negotiate a better price or absorb the difference between the Medicare payment and their purchase price. For many practices, these are not viable options.

Phase 1 of the Model Could Undermine Continuity of Care and Increase Costs to Patients and the Health Care System

Section 1115A of the Act authorizes CMS to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The Agency has provided no documentation that across the board cuts as proposed in phase 1 will preserve or enhance the quality of the care furnished to Medicare beneficiaries. CMS has not cited any studies that demonstrate that a reduction in reimbursement for drugs administered to treat cancer, rheumatoid arthritis, and macular degeneration, for example, will preserve or enhance the quality of care. It appears that the Agency expects that phase 1 will be either budget neutral or actually reduce expenditures; thus this phase appears focused exclusively on reducing costs.

Yet, there is a clear possibility that phase 1 will drive higher costs to Medicare and patients. We anticipate that phase 1 of the model would accelerate the nearly decade long migration of the administration of Part B drugs from physician offices where patients receive their ongoing care, to hospital based outpatient sites of care which are more expensive and pose additional patient barriers (including geographic) as well as higher out-of-pocket costs for patients. The Community Oncology Practice Impact Report*: The Changing Landscape of Cancer Care*, issued October 21, 2014, documents the changing oncology landscape including the growing number of closed community oncology clinics, practices struggling financially, practices sending their Medicare patients elsewhere for treatment, practices acquired by hospitals, and practices that have merged or been acquired. Furthermore, in the 2016 Medicare physician fee schedule payment rule, CMS put four drug administration codes on the list that the Agency wants reviewed as potentially misvalued because the Agency thinks the codes are overvalued. All four codes include chemotherapy administration. This means that at the same time that

physicians are absorbing the Part B payment cuts, they could also be facing cuts in their payments for administering the drug.

Why the accelerating migration to hospital based outpatient sites which are more expensive?

Because the ASP includes payments that are heavily discounted to reflect volume, prompt pay, and other such adjustments, it does not reflect the true relatively higher prices paid by many physician practices with relatively low-volume purchases as compared to entities with larger purchasing power, capital reserves, and governmentally mandated rebates. Even with the current 4.3 percent add-on (after accounting for the sequester), Medicare reimbursement may not cover actual costs, especially for physician practices that face high wholesaler fees or state and local drug taxes, which are not counted in the ASP. This general problem is exacerbated by other issues such as drug compounding regulations and other potential new safety-related rules that reduce drug availability and/or increase cost of drug storage and administration.

Hospital outpatient departments would also be subject to the proposed changes but are expected to fare better than physician offices because they can usually purchase drugs at a lower cost than physicians and are therefore less likely to lose money on a drug. About half of hospitals providing Part B drugs get 340B drug rebates, which reduce their drug costs. (Not surprisingly, a large number of the community oncology practices were absorbed by 340B hospitals.) The U.S. Department of Health & Human Services Office of the Inspector General (OIG) found that in 2013 hospital-based providers paid the 340B ceiling prices to acquire Part B drugs an estimated $2.2 billion yet they were reimbursed $3.5 billion for these purchases by Medicare. OIG stated: Part B paid [340B hospital] covered entities a total of $1.3 billion (58 percent) more than the cost of the drugs.[2]

Physician practices are not eligible for 340B rebates and lack size and patient count to negotiate equivalent discounts comparable to 340B rebates. (If such rebates were easy to extract, hospitals would not require the government mandated 340B rebates.) Also, even in cases where the hospital's cost is higher than Medicare's reimbursement rate, losses on the drug will have less impact than in physicians' offices because for most drug administration services, hospitals are paid at least 25 percent more than physicians delivering the same service in their office.

As phase 1 is implemented, physician practices that are not able to obtain Part B drugs at the new rates will not be in a position to continue to provide care to their patients and will need to migrate their patients to hospital outpatient offices. Medicare and its beneficiaries will pay more as services shift into the hospital setting where a number of studies have found that treatment costs and patient co-pays are considerably higher than in physician offices. Analyses of both Medicare and private insurer data suggest, for example, that costs for a course of chemotherapy and related care are at least 24 percent more in outpatient departments than physician offices.

The Agency specifically requests feedback on the impact of the model on small practices. For several years, the AMA has continued to express our concern that ASP plus six percent is insufficient to reimburse small physician practices for the actual costs of Part B drugs. It should be no surprise that

[2] U.S. Department of Health & Human Services, Office of the Inspector General, Part B Payments for 340B-Purchased Drugs, November 2015.

hospitals and large health systems are able to obtain discounts and lower negotiated prices that physician practices are not able to secure because of volume differentials. Since ASP includes such discounts, it is not difficult to understand why physician practices have struggled under ASP plus six percent. This is not a novel or new concern. The GAO had been in the in the midst of studying how Medicare's payment for drugs covered under Medicare Part B compares to providers' actual acquisition which the AMA has strongly supported when this proposed model was issued. We have cited this concern as driving physician practices to direct their patients to hospital-based outpatient practices or selling their practices altogether to hospitals. Practices that are small, rural and/or located in economically disadvantaged areas are especially vulnerable because in addition to paying more for drugs, they often have higher costs for shipping and other associated costs along with fewer opportunities to spread costs among privately insured patients. Many will be forced to send their Medicare patients, and perhaps all their patients, to hospitals for outpatient drug treatment. A significant number may also be forced to sell their practices to hospitals, accelerating a trend that has led to Medicare drug spending growth that between 2009 and 2012 was four times as rapid in hospitals as in physician offices.

Model Methodology Will Undermine Validity of Findings and Generalizability

The AMA appreciates that CMS has proposed what the Agency believes is a design that accounts for selection bias, incorporates stratified random sampling, and ensures adequate statistical power for sub-group analyses. Yet, an essential principle of sound health services and clinical study design is to minimize variables between the comparison groups, except the intervention. Having a national cohort of patients with a very large number of diseases, disparate co-morbidities, and tremendously varied treatments, along with care that is delivered in widely disparate settings and conditions that are not specified or organized will make it nearly impossible to conclude that any effects (or lack of effects) are due to specific intervention(s). Instead of targeted sampling with appropriate study controls, the model methodology seeks to use crude measurement (primarily claims data) and sheer volume to construct an evaluation model using group randomized trial methods. We urge CMS to reconsider this approach given the anemic evaluation methods identified to assess quality and/or patient health outcomes, two essential required components of §1115A models.

Our concern is deepened by the proposed evaluation methods the Agency intends to use in order to measure patient health outcomes and quality. The heavy reliance on claims data to assess the various strategies is unlikely to capture a host of negative patient impacts and adverse patient health outcomes which are likely to include lack of access, adverse drug events, fragmentation of care, and lack of care coordination when site of care is changed. Given the potential negative clinical consequences of phase 1, the shortage of specified outcome measures and methods to capture relevant clinical information places Medicare beneficiaries at risk without any meaningful mechanism for the Agency to identify and take corrective action to address emerging and widespread harm as the model unfolds.

Further, claims data are not adequate to assess quality and patient health outcomes which is an essential requirement under §1115A waiver authority. The Agency proposes to augment their heavy reliance on claims data <u>possibly</u> with surveys of beneficiaries, suppliers, and providers to assess whether "the intervention reduces costs while improving quality of care…[and] could include assessments of patient experience of care, prescribing and utilization patterns, health outcomes, Medicare expenditures, provider and supplier costs, and other potential impacts of interest to stakeholders." CMS has not specified how, where, why, and when such surveys will be administered and analyzed or how they will ensure consistent,

ongoing feedback to the surveys. This is a national, multi-prong test model that is mandatory and involves thousands, if not hundreds of thousands of patients, and thousands of health care providers. The lack of a specified set of measures and methods/instruments for gathering reliable, consistent evaluation information other than claims data represents a significant shortcoming of the model.

Based on the existing description of the model we have questions on its inferential capability and external validity. If the Agency modifies this proposal to include important patient protections and ensure exclusions needed before randomization to protect the most vulnerable patients from harm these questions will be magnified. If such exclusions are not provided, Medicare beneficiaries will be forced to bear the risk of this experimentation without implementation of the basic safeguards in studies involving clinical interventions that are typically required such as oversight by an institutional review board (IRB) and informed consent. We urge the Agency to reduce the scope of any new model and include strong ongoing oversight to monitor emerging patterns that negatively impact patients so that fewer exclusions are needed to protect patients and the relevance of the findings is greater and context is transparent and carefully scrutinized.

Equally concerning from a design perspective, the Agency acknowledges the likely overlap between the model and the Medicare Shared Savings Program, the Medicare Intravenous Immune Globulin Demonstration, and other Innovation Center payment models, such as the Oncology Care Model and the Bundled Payments for Care Improvement initiative. Nonetheless, CMS has suggested that it would not exclude beneficiaries, suppliers (including physicians), or providers in other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program, from this proposed model. The suggestion that the Agency would not exclude other models, initiatives, and specially designed and controlled programs, underscores the methodological infirmities of the current proposed model and the potential to undermine the methodological rigor of the other long-standing efforts that would layer another model design over existing models.

The Model Does Not Mitigate Potential for Patient Harm

Congress included a number of patient protections as part of the Agency's §1115A waiver to ensure input on and oversight of these models likely as stand-ins for informed consent and the IRB processes. The Agency's proposed model does not adhere to any of the Section §1115A protections. The proposed test model would involve an estimated 75 percent of Medicare beneficiaries receiving Part B drugs who would not be able to opt-out of the model. Given the complexity of the model and proposed overlay of it with other models, MACRA implementation, and PAMA reporting requirements, this model will directly impact patient options and access to medical care that they would otherwise receive. The model does not contain any quality or patient outcome mechanism to monitor and gather ongoing information to ensure that widespread patient harm is not occurring in a given phase or arm of the model—essentially a mechanism that would be equivalent to IRB oversight.

Patients on an established course of treatment who are stabilized could be negatively impacted when a targeted treatment is terminated due to the proposed model under phases 1 and 2. Most older Medicare patients, who are more likely than younger people to be treated in physician offices and may have limited transportation options and have multiple co-morbidities that need to be actively managed by someone knowledgeable of their medical history, are most at risk. Ultimately, however, widespread healthcare disparities could occur based largely on the selection of sites for a hastily-executed federal model that has

the potential to reduce availability of care for a variety of life-threatening or life-changing conditions such as cancer, rheumatoid arthritis, and macular degeneration. Given that beneficiary participation is mandatory, the scope of the model is national, stakeholder engagement limited, and omission of meaningful §1115A patient protections, the lack of informed consent from participating Medicare beneficiaries is inconsistent with the Administration's initiatives to increase shared decision-making and patient centered care. It stands in marked contrast to an equally large research effort—the President's Million Genome Project—which is voluntary and patients are empowered to be involved and informed consent is carefully considered and ensured.

In both phase 1 and phase 2 of the model the Agency indicates that the patient protections will include the existing adverse determination appeals process which is available to Medicare beneficiaries, providers, and suppliers. Presumably, this appeals process could be used to seek access to appropriate treatment by their treating physician at ASP plus six percent. (It is not clear that the foregoing would be an issue subject to appeal.) The AMA, MedPAC, and numerous patient advocates have identified persistent and well-documented delays, complications, and difficulties faced by beneficiaries who attempt to avail themselves of this appeals option. This patient "protection" places tremendous burden on the beneficiaries and their treating physicians and the prospect of successfully securing an appropriate determination is ambiguous since it requires some third party with no prior knowledge of the patient second guessing their physician's determination that an alternative course of treatment is necessary at ASP plus six percent or without use of another strategy.

The Agency also proposes a Pre-Appeals Payment Exceptions Review process to resolve disputes arising from the policies implemented for phase 2, but not phase 1. CMS states that the Pre-Appeals Payment Exceptions decisions would be issued, in writing, within five business days of receipt of the request for a payment. Once again, it is not clear what criteria will be utilized to evaluate these requests, the qualifications of the reviewer, and the relief that can be provided. This patient protection will delay a patient's treatment, and is not subject to review so it lacks any meaningful accountability.

Given the scale of this model, the patient protections are threadbare and do not provide for active monitoring to assess negative patient outcomes in real time. This underscores that the model as constructed is too large with too many unknown variables (because more limited phase 1 model testing has not been done).

Agency Exceeded §1115A Authority

CMS has not complied with the requirements for a §1115A model and has exceeded its statutory authority. Section 1115A includes requirements that the Agency must adhere to when implementing phase 1 and phase 2 models. Under phase 1, CMS may waive a sweeping number of statutory provisions governing the Medicare program, but does not have the same authority to do so for expansion under phase 2.

The Agency has proposed a phase 1 and phase 2 model. On its face, the Agency has not met any requirements that apply to a phase 2 model. Assuming that the Agency intended that phase 1 and phase 2 models are really meant to be phase 1 models under §1115A, the Agency still has not complied with the requirements under phase 1 authority.

First, CMS is proposing a highly complex national model that should be characterized as potentially hundreds of models without having engaged in adequate consultation with clinical and analytical experts with expertise in medicine and health care management for each permutation proposed. If the Agency has done so, we urge CMS to detail such consultations.

Second, the Agency has not sought input from impacted stakeholders such as physicians and patients through, for example, town halls as required under §1115A authority. Most models involve extensive planning and input from impacted stakeholders and are typically voluntary. The abbreviated notice and projected implementation timeframe for a model of this scope and complexity is unprecedented. The level of planning for a model one-tenth the size of this model would be extensive to ensure implementation was feasible and real-world clinical conditions consistent with the model.

Under §1115A, the model should be limited in scope and have a well-defined population with specified deficits in care as required by the statute. All Medicare beneficiaries with all conditions is not likely what Congress intended by this requirement when conferring the Agency with authority to undertake limited studies under phase 1 models. Given the potential for this authority to serve as an end run around congressionally mandated Agency obligations and beneficiary rights, the statutorily specified §1115A phase 2 requirements are clearly designed to prevent the national roll-out of untested hypotheses to the majority of Medicare beneficiaries that could prove harmful to patients or drive higher costs. It is unreasonable to conclude therefore that Congress intended a national roll-out could be achieved by simply fashioning a model as phase 1.

The national scope and scale of this proposed model—phase 1 and phase 2 combined—is best characterized as an expansion under §1115A(c) without having complied with §1115A(b)(4). Specifically, the implementation on a nationwide basis of a model requires that the Agency conduct an evaluation of "a" model under §1115A(a). The Agency's phase 1 and phase 2 models are not properly structured as a model in the first instance and are unlikely to obtain the type and quality of data to evaluate the outcome required under (b)(4). The Agency indicates that it will primarily rely on claims data to evaluate the model which is unlikely to provide information on the "quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness." The Agency is required to make the results of each of the foregoing available to the public in a timely fashion before expansion of the model nationwide. CMS has not. The scope and complexity of this proposed model is contrary to the clear statutory requirements for exercise of §1115A authority. In short, the Agency appears to have jumped over the requirement to conduct a phase 1 model that, following analysis of its impact, would be expanded nationally.

Timeline for Implementation Not Workable

CMS is proposing to implement these sweeping changes to Medicare payment policy in 50 percent of the United States based on a 60-day notice and comment period. In addition to concerns related to the underlying concept for this model, the AMA is concerned by its timing, evolution and logistical challenges. As previously noted, the model calls for an abrupt and mandatory shift in payment policy for certain localities while others continue under the existing policy.

It is proposed that implementation of phase 1 will occur 60 days from the issuance of the final rule. Thus the initial round of pay changes could occur before the end of 2016 and then be expanded next year with

up to five additional drug payment modifications that have yet to be described in any detail. And the planned implementation dates do not provide time for adequate outreach, education and preparation for physicians and patients in the affected areas. Under normal conditions, the AMA generally estimates that after a final agency rule is finalized six months is needed to conduct outreach and education concerning a new national program and providers then need an additional six months to prepare for compliance including planning, training, and adjustments to practice. The Agency proposes to roll this out simultaneously with MACRA and PAMA implementation. The staffing and resource bandwidth required for this level of change requires a substantially longer lead time.

The rapid roll-out will exacerbate the administrative confusion that would occur even under a more lengthy timeframe because in some locations the price will remain unchanged and in others subject to multiple reimbursement changes. Practices will have little to no time to plan for such changes including developing and implementing patient transition plans to other providers who are able to provide the patient's established course of treatment such as hospital outpatient offices. Since CMS also proposes to include other §1115A models and CMS initiatives, these providers will not have adequate time either to assess the impact on their patient panels and their model and make appropriate adjustments to minimize patient harm and, in some cases, to ensure practice sustainability.

The implementation timeframe for phase 2 of the model will further overwhelm physician practices. While we are supportive of the Agency's efforts to outline a number of options under what the Agency characterizes as "phase 2," the proposed timelines for notifying and soliciting public comment and then for implementation are not reasonable. CMS proposes that any approved pricing changes under phase 2 would allow for the public to provide feedback for 30 days and then the new strategies would be made public 45 days ahead of implementation. We appreciate that allowances are made for securing additional public feedback, but the 30 day comment period is too short for physicians and physician organizations to consult with clinicians, researchers, and other experts and then develop the needed detailed feedback and recommendations—particularly if, like this notice, it is published all at the same time. The 45-day-notice is not adequate either to ensure practices are made aware of the changes, and they are able to make appropriate adjustments including arranging to have patients transferred, if necessary, to ensure continued access where available to treatments that meet their medical needs. All outreach and educational activities should be done in coordination and concert with physician organizations and should allow a minimum of six months for outreach and an additional six months to prepare for implementation.

Undermines MACRA and PAMA Implementation

Phase 1 and phase 2 of this model envisions multiple changes in drug payments occurring simultaneously with each other and with the implementation of MACRA and PAMA. Physician and CMS resources that could be better spent preparing for participation in MACRA will be diverted to the model. Evaluation of the various modifications in Part B drug reimbursement will be crippled by the very difficult challenge of disentangling the impact of all the concurrent policy changes. It will also be virtually impossible to accurately compare drug spending among physicians and make related payment changes as required under both current law and MACRA. The consequences could be especially problematic if CMS makes 2017 the first performance year and baseline against which future improvement will be measured under MACRA. Furthermore, a final PAMA rule is expected imminently, and it is anticipated that a subset of physician office based laboratories will have to implement investment in reporting capacity including education, training, and infrastructure to provide the detailed reporting on the price of every private payer

amount for each test subject to the reporting requirement provided by the practice. Two of the most significant changes to occur in decades to how Medicare pays for services that are currently on the physician fee and clinical laboratory fee schedule will be rolled out simultaneously with this proposed model. The Agency is laying the foundation for a perfect storm of regulatory and administrative burdens that will overwhelm physician practices as they struggle to adapt to the new MACRA merit-based incentive payment system or alternative payment model requirements and PAMA reporting.

Undermines the President's Precision Medicine Initiative and the Cancer Moonshot Initiative

Over the past two years the Administration and Congress have touted the importance of genetic and genomic discovery and the corresponding translational work that has resulted in testing that enables targeted treatment. The sequencing of the human genome and breathtaking advances in computing capacity are ushering in a new dawn in medicine in which highly individualized and targeted treatments are progressing rapidly in areas of medicine such as oncology, infectious diseases, newborn screening and increasingly other areas of clinical practice. The foregoing has begun to turn on its head population-based models of patient care. The Food and Drug Administration (FDA) is approving a larger percentage each year of new drugs that can be specifically targeted to treat patients based on both inherited and acquired genetic variants. We have reached a new frontier where population-based, randomized clinical trials are not the only source of high-quality scientific and clinical evidence.

The President's Precision Medicine Initiative and the recently announced Cancer Moonshot Initiative will be hindered by phase 1 because it will limit patient access to treatments that are targeted to patients' specific needs. In many cases, biologic and specialty drug treatments target a particular cell or biomarker, making the treatment more efficient and safer, but sometimes more expensive, than conventional treatments. Yet under phase 1, there will be tremendous pressure to not use such treatments. This is best understood in the context of drugs that inhibit tumor growth that, while expensive, are only prescribed to patients who would benefit from them.

Under phase 2, there are two strategies that have the potential if not properly structured to also hinder a patient's ability to obtain the appropriate targeted treatment. First, CMS proposes to provide equal payment for therapeutically similar drug products (called reference pricing). However, due to advances in genomic and genetic knowledge that enable drugs to target specific variants, the notion of therapeutically similar drug products is becoming progressively anachronistic—particularly for new drugs and treatments. The Agency states that: [w]hen multiple drugs in a group have varying levels of effectiveness, the payment for the most clinically effective drug in the group could be paid based on a benchmark while the payment for the remaining products could be adjusted downward based on their effectiveness in relation to the most clinically effective drug. But, for whom is it most clinically effective? How CMS defines levels of effectiveness is relevant, but this again raises an overriding concern: what is likely to be clinically effective for a specific patient is a multifactorial determination based on a host of factors. The levels of effectiveness as determined by CMS could be based on population-based considerations that do not account for patient specific conditions or biomarkers. A second strategy outlined in the proposed rule to vary prices for a given drug based on its varying clinical effectiveness for different indications, often called "indications-based pricing," raises similar questions and careful consideration on how such a strategy is structured. CMS states: "[d]rugs are often indicated for more than one condition and may be more effective when used in one condition than another. For example, if a new drug is introduced with indications for treating two types of cancer and this drug did no

better in clinical trials than existing treatments for the first type of cancer and significantly better than existing treatments for the second, our use of indications-based pricing might result in lower payments when the drug is used to treat the first type of cancer and higher payments when the drug is used to treat the second type."

Once again the type of evidence and example provided by the Agency raises questions about how these strategies will be deployed. For example, reliance on randomized clinical trials in the context of targeted treatments might not be appropriate. CMS should include a clear discussion of various methods for ensuring targeted treatments are evaluated properly and ethically. For example, basket studies, unlike randomized clinical trials, lump together different kinds of cancer, are much smaller than the usual studies, and are designed without control groups of patients who for comparison's sake receive standard treatment. The FDA has indicated that drug approvals could be based on basket study data alone. There are particular concerns for personalized medicine with regard to how reference- and indication-pricing would be conducted. More generally, the AMA would like to discuss more fully with the Agency the categories and conditions that CMS would consider developing a model to test reference- and indication-pricing and how it would evaluate quality and patient health outcomes.

Exceptions: National Drug Shortages

The Agency proposes to exclude drugs that are listed on the FDA's national drug shortage list. While the AMA appreciates the Agency's effort to minimize the possibility that the model will exacerbate national drug shortages, the Agency does not propose to include drugs that are part of regional shortages. Regional drug shortages are far more common than national shortages and equally costly as well as challenging for physician practices to plan around and to find Part B drugs at the existing ASP plus six percent to ensure continued access to a patient's established course of treatment. The AMA strongly urges CMS to exclude drugs that are part of national and regional shortages in the model, and payment should revert back to ASP plus six percent. Furthermore, the AMA strongly urges the Agency to provide an overview that has been conducted by CMS to establish that the ASP plus six percent policy has not contributed to the persistent and increasingly common drug shortages that have disrupted care, harmed patients, and generated additional health care costs.

"Phase 2" and Alternative Options

The AMA appreciates that CMS had identified a number of options under "phase 2."[3] We outline some preliminary feedback which is limited due to the lack of sufficient details concerning each payment strategy. We also have included additional recommendations for options that CMS should consider after the Agency has rescinded this proposed model and engaged in dialogue with interested stakeholders to structure appropriately sized and designed §1115A phase 1 models.

The AMA would like to work with CMS, and other stakeholders to develop model alternatives that would specifically address the high cost of Part B covered drugs and biologicals and improve patient health

[3] Once again, we are left to concluded that the reference in this context to phase 2 of §1115A model, must be a drafting error since neither arm properly qualifies as a phase 1 or phase 2 model, but the Agency has not complied with the requirements related to a phase 2 model.

outcomes without the pronounced risk of serious, negative unintended consequences of this proposed model's phase 1 and phase 2. We propose to work with CMS and other interested stakeholders on one or more of the following value based pricing strategies: outcomes-based risk-sharing agreements; targeted discounting or elimination of patient coinsurance amounts; and digital tools to support clinical decisions for appropriate drug use and safe prescribing. We would also like to discuss with CMS an additional option that was not proposed in the model, to reduce manufacturer vial sizes to lower costs.

Utilize Coverage Methods that Encourage More Options in Vial Size. We urge CMS to solicit additional input and then develop a model that would compel or incentivize manufacturers to provide more options in the sizes of vials available for purchase. There is some indication that reduction in the size of vials would reduce cost per unit and reduce waste.

Risk-sharing agreements based on outcomes. The AMA urges CMS to engage stakeholders in a fuller discussion of the phase 2 proposed strategy whereby manufacturers would enter into voluntary risk-sharing agreements with CMS to link health care outcomes with payment. Since these agreements tie the final price of a drug to results achieved by specific patients rather than using a predetermined price based on historical population data implementation, tracking, and reporting the outcomes could impose administrative burdens on physicians and patients. The AMA agrees that this model should include specified outcome measures and should be sufficiently robust to capture short- and long-term improved clinical outcomes. However, we are very concerned that the Agency has proposed that value would be measured "through data collection likely, though not necessarily, provided by the prescriber" and intended to address factors such as long-term safety and outcomes, effect on an individual patient, patient adherence, or impact on utilization and costs. It would be inappropriate to impose this reporting burden on physicians and the reporting obligations must be shouldered by manufacturers given the administrative costs associated with the detailed information that the Agency has indicated should be captured, analyzed, and reported.

Evidence-based Clinical Decision Support. The AMA supports additional consideration of the proposal to offer an online tool that supports prescriber clinical decisions through education and provides feedback based on drug utilization in Medicare claims. The Agency proposes to develop a single online portal to provide the clinical decision support. The AMA strongly urges CMS to consider that such support tools must be designed by appropriate physician specialties, integrate into clinical practice, and meet usability requirements. Through further discussions and work involving interested medical specialties, CMS, and clinical practices, this activity could be fashioned to qualify as a MIPS Clinical Practice Improvement Activity (CPIA). We also urge CMS to conduct an environmental scan of existing clinical decision supports that already exist to avoid reinventing from whole cloth such a decision support given the challenges of curation and potential issues with usability and integration with clinical flow. The Agency also proposes creating an online source of data that would provide feedback to physicians in this arm of the phase 2 on their prescribing. The AMA strongly supports this provision as it provides information that allows physicians to evaluate their prescribing relative to others in a robust, ongoing, and confidential manner without penalties.

Targeted Elimination of Co-Pays. The Agency proposes to waive beneficiary cost sharing from the current 20 percent, meaning that the copayment that is associated with a HCPCS code in phase 2 of the model could be reduced by CMS to a value that is less than 20 percent and could be waived completely. In addition, consistent with cost sharing approaches for Part B drugs, CMS has proposed that beneficiary

cost sharing will not exceed 20 percent of the total model-based payment amount for the Part B drug. The AMA supports developing a model to discount or eliminate patient coinsurance amounts for services that are determined to be high in value, and believes CMS should engage with the physician community in the development of such a model. The AMA would encourage CMS to specify which drugs, and the AMA would welcome the opportunity to provide additional feedback.

The AMA appreciates the opportunity to provide comments and looks forward to working with CMS to develop a number of models that will test various value-based payment models for Part B drugs that are likely to reduce overall costs, promote quality, and improve patient health outcomes. We also urge CMS to consider that a number of these models could be fashioned as part of MACRA MIPS CPIA and that opportunity should be leveraged to encourage uptake and participation. If you have questions, please contact Sharon McIlrath, , Assistant Director, Division of Federal Affairs at 202-789-7417 or Sharon.Mcilrath@ama-assn.org.

Sincerely,

James L. Madara, MD